IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES *ex rel.* HARRY F. FRY, M.D.,	:	**CIVIL ACTION NO. 1:03-CV-00167**
Plaintiffs,	:	**Judge S. Arthur Spiegel**
v.	:	**Magistrate Judge Timothy S. Black**
THE HEALTH ALLIANCE OF GREATER CINCINNATI, *et al.*,	:	**ORAL ARGUMENT REQUESTED**
Defendants.	:	

DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT

Defendants—The Christ Hospital, The Christ Hospital, Inc., The Health Alliance of Greater Cincinnati, and Ohio Heart & Vascular Center, Inc.—hereby submit this Joint Motion for Summary Judgment. For the reasons set forth in the attached memorandum in support, the Court should grant summary judgment to defendants and dismiss this case with prejudice. Because of the legal complexity of the Anti-Kickback Statute, the False Claims Act, and the United States' theory here, Defendants request oral argument.

Date: November 24, 2009

Respectfully submitted,

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MEMORANDUM IN SUPPORT

COMBINED TABLE OF CONTENTS AND SUMMARY

The Anti-Kickback Statute "makes intent a key element." *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 683 (W.D. Ky. 2008). If the defendant is alleged to have "offered or paid" remuneration, the United States must prove that the defendant did so with the intent "to induce" referrals. 42 U.S.C. § 1320a-7b(b)(2); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995). If the defendant is alleged to have "solicited or received" remuneration, the United States must prove that the defendant did so "with intent to allow the remuneration to influence the reason and judgment behind one's patient referral decisions." *United States v. LaHue*, 261 F.3d 993, 1002 n.11 & 1004 (10th Cir. 2001) (internal quotation marks omitted).

"A party against whom summary judgment is sought is not entitled to a trial simply because he has asserted a cause of action to which state of mind is a material element." *Stepanischen v. Merchants Despatch Transp. Corp.*, 722 F.2d 922, 929 (1st Cir. 1983).

Here, evidence of criminal intent is entirely lacking. Agents of The Christ Hospital and The Health Alliance explained that Heart Station panel time—the alleged remuneration—was "designed wholly for other purposes" than to induce referrals, namely, assuring proper patient care. *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000). Likewise, Ohio Heart cardiologists treated patients at The Christ Hospital because it offered great equipment and superb nursing care, not for the criminal purpose of soliciting or receiving panel time

To create a jury question, the United States must show that an employee of each defendant was motivated not only by these legitimate reasons but also by illegal ones. It cannot do so for numerous reasons. First, as for defendants' use of volume statistics, courts have recognized that "physicians who routinely make greater use of the facility are expected to take on more responsibility and become more involved than a physician who seldom uses the facility." *United States ex. rel Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 864 (C.D. Ill. 2003). Second, most physicians did not know how administrators assigned panel time. Third, panel would have been distributed in roughly the same proportion no matter how it was allocated. Fourth, panel time's value depended on each cardiologist, as the opportunity to do panel work was not generally valuable across all cardiologists. Fifth, numerous physicians did not consider panel to be an inducement. Sixth, no evidence exists that agents for The Christ Hospital or The Health Alliance had any motive, personal or otherwise, to offer kickbacks.

Under the False Claims Act's "falsity" element, "the statement or conduct alleged must represent an objective falsehood." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). "[I]mprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false." *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999); *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000). The evidence now shows that the United States has failed to establish an objective falsehood. First, the United States has admitted that it did not provide specific guidance on the issue here. Second, that lack of guidance is inexplicable given that many entities interpreted the Anti-Kickback Statute like defendants in response to the United States' own request for public comments. Third, evidence confirms that other hospitals looked to similar volume statistics, whether directly or indirectly, in making panel-allocation decisions.

The United States cannot resort to the implied-certification doctrine because the Anti-Kickback Statute does not "expressly state[]" that health care providers "must comply in order to be paid" under health care programs. *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001); *see United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009); *United States ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00-cv-4863, 2003 U.S. Dist. LEXIS 27469, at *23 (E.D. Pa. Aug. 14, 2003).

To rely upon the express-certification theory, the United States must show that a defendant expressly "certifies compliance with a statute or regulation as a condition to governmental payment." *Mikes*, 274 F.3d at 697. The applicable certification underlying a claim, in other words, must expressly "state that compliance is a prerequisite to payment." *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1218 (10th Cir. 2008). In contrast, "[a] general statement of adherence to all regulations or statutes governing participation in a program through which federal funds are received is insufficient as a basis of False Claims Act liability." *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 501 (S.D. Tex. 2003), *aff'd*, 111 Fed. App'x 296 (5th Cir. 2004). Here, the United States relies on statements that do not certify compliance with the Anti-Kickback Statute or that broadly certify compliance with all regulations. It thus cannot rely upon the express-certification theory.

Some courts have permitted False Claims Act plaintiffs to proceed on the theory that the United States conditioned health care payments on compliance with the Anti-Kickback Statute. But this law was decided at the motion-to-dismiss stage where the courts had to accept as true the allegations that compliance was a condition of payment. *See United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259-60 (11th Cir. 2005). This law could not

1008, 1035 (D. Nev. 2006). Thus, because the United States has not demonstrated a fact dispute on the False Claims Act's elements, no fact dispute exists on its common-law claims.

Because MDA allocated panel time between 2001 and 2004, The Christ Hospital and The Health Alliance did not "offer[] or pay[]" panel time to induce referrals during those years. 42 U.S.C. § 1320a-7b(b)(2). The United States has also failed to establish that they entered into a False Claims Act conspiracy. 31 U.S.C. § 3729(a)(3). Under that conspiracy provision, the United States must prove that defendants "agreed upon a fraud scheme" and "intended 'to defraud the Government' by [it]." *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2130 (2008); *see United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343 (5th Cir. 2008). Here, the evidence shows that MDA decided upon its panel-allocation methodology independent of the other defendants, which negates the possibility of a conspiracy.

A claim can only be false if the services underlying it were tainted by an Anti-Kickback Statute violation. That is the entire basis for the "legally false claims" theory. *See Mikes*, 274 F.3d at 696-97. As a result, the United States must present evidence to meet every element of the Anti-Kickback Statute for each of the hundreds of thousands of claims it alleges is false. But it lacks sufficient evidence on most claims. For instance, the United States has not presented sufficient evidence with respect to all claims by physicians who did not know the manner that panel was allocated. And the United States has presented no evidence on whether many other physicians knew how panel time was assigned. But it can no longer "rest on the mere allegations in [its] pleadings." *McKenzie v. BellSouth Telecomms., Inc.*, 219 F.3d 508, 512 (6th Cir. 2000).

The False Claims Act's reverse-false-claim provision imposes liability on a defendant who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). If the alleged "obligation arises if and only if a defendant makes a false statement or files a false claim . . . , an action under [31 U.S.C. § 3729(a)(7)] will not lie." *Am. Textile Mfrs. Inst., Inc. v. The Limited, Inc.*, 190 F.3d 729, 734 (6th Cir. 1999). Here, the United States has not uncovered evidence that defendants had an obligation to pay apart from their allegedly false certifications.

TABLE OF AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

The Christ Hospital, a non-profit community hospital, takes pride in providing high-quality care for its patients, and consistently receives national recognition for, among others, its cardiology care. (TCH Fiscal Accomplishments 2004, at 2, App. 969.) To provide first-rate cardiac care, the hospital must include in its range of services a "Heart Station," where patients undergo noninvasive testing critical to diagnosing and preventing cardiac disease. (*See* Wall Dep. at 15-18, App. 287-88.) As part of its patient-care duties, the hospital must ensure that the testing there is both "timely and [read] by qualified" physicians. (Dep. Ex. 71 at 3, App. 408.) In addition, when a physician ordering testing has not identified a specific cardiologist to read the test, the hospital must, of necessity, assure that a cardiologist timely reads the test. (*Id.*) To do so, the hospital assigned reading time, also referred to as "panel time," in the Heart Station to interested, qualified cardiologists.

In the 1980s, hospital administrators grew concerned that cardiologists who rarely practiced there were failing to provide timely coverage for performing or reading these tests. (Tempel Dep. at 23-25, 67, App. 251-53, 263.) Experience at the hospital showed that "patients were put at risk by physicians who had privileges but weren't present" to perform or read the tests. (*Id.* at 52, App. 257.) By the same token, common sense showed that "[t]he more time [physicians] spend [at a hospital] the easier it is to . . . find time to read the panels." (Jenike Dep. at 13, App. 159.) To remedy the problem, therefore, administrators decided to allocate panel time to doctors in proportion to how often they were "there at the hospital." (Tempel Dep. at 15-16, 20, App. 246-47, 249.) They looked to objective statistics of a physician's procedure volumes to do so. (*Id.*)

In the health care field, The Christ Hospital administrators were not alone in considering physician volumes, whether directly or indirectly, in decisionmaking. "It's part of standard

business practice at every hospital in the country" to look at volume statistics for many decisions. (Croushore Dep. at 26, App. 61; *see* Ronning Expert Report at 31, App. 907.) Indeed, at many hospitals, panels were "based on the physicians who actually practiced at the hospital." (Wietmarschen Dep. at 18, App. 323; *see* Desai Dep. at 38-39, App. 78.) Similarly, many hospitals assigned physicians a block of operating-room time based on volumes. (*See* Seim Dep. at 166, App. 217.) And hospitals also conditioned staff privileges on volume numbers as well. (*See* Univ. Hosps. Health Sys. Public Comments at 7, App. 669.)

This litigation calls into doubt, for the first time, these widespread practices. Specifically, the United States and Dr. Harry Fry have targeted The Christ Hospital, The Christ Hospital, Inc., The Health Alliance of Greater Cincinnati, and Ohio Heart & Vascular Center, Inc. (collectively "defendants"), seeking over a billion dollars based on the use of volume metrics in staffing decisions. To that end, the United States asserts seven counts over the manner in which panel time at The Christ Hospital was allocated between 1997 and the first quarter of 2004. All seven rely upon the theory that assigning panel time based on volumes violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). That alleged Anti-Kickback Statute violation underlies the United States' four counts under the False Claims Act, 31 U.S.C. § 3729(a), as well as its common-law claims of mistake of fact, unjust enrichment, and disgorgement. (R.53 at 23-27.)

Despite its far-reaching accusations, the United States admits that, during the relevant period for which it seeks over a billion dollars, it never "published guidance specifically addressing" whether a hospital can consider volumes in allocating panel time or making similar decisions like assigning operating-room time, creating emergency-call lists, or awarding medical-staff privileges. (United States' Admissions at 20, 35, App. 722, 737.) Indeed, this is the first action it has brought on those facts. (*Id.* at 33, App. 735.) Nor, it bears noting, has the

United States ever alleged that any medically unnecessary services were performed as a result of what it alleges is an illegal kickback scheme. In sum, the United States seeks over a billion dollars based upon the performance of necessary services at an award-winning cardiology unit.

While all agree that volume statistics, in part, were used in setting panel assignments, that fact alone is hardly surprising, nor does it come close to proving a violation of the Anti-Kickback Statute or the False Claims Act. *First*, the United States lacks sufficient evidence to show that defendants' agents harbored the criminal intent necessary under the Anti-Kickback Statute. The Christ Hospital and The Health Alliance are alleged to have "offered or paid" remuneration in violation of that statute, which requires the United States to show that these defendants did so with the intent "to induce" referrals. 42 U.S.C. § 1320a-7b(b)(2). Yet, as hospital administrators have repeatedly explained, Heart Station panel time—the alleged remuneration—was "designed wholly for other purposes" than to induce referrals. *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000). In truth, administrators were *required* to offer cardiologists panel time to allow for needed patient care. And they did so to ensure "that the panel time was covered" in a fair, efficient, and timely manner. (Wietholter Dep. in *UIMA v. MDA* at 29, App. 317.) This is hardly the making of a billion dollar fraudulent scheme.

To the same end, Ohio Heart is alleged to have "solicited or received" remuneration, 42 U.S.C. § 1320a-7b(b)(1), and the United States must prove it did so with the intent "to allow the remuneration to influence the reason and judgment behind [its] patient referral decisions." *United States v. LaHue*, 261 F.3d 993, 1002 n.11 & 1004 (10th Cir. 2001) (internal quotation marks omitted). But Ohio Heart cardiologists referred patients to The Christ Hospital because the hospital offered "great equipment" and "superb nursing care" and because they "fel[t] like

[their] patients [were] getting the best care" there, not with any intent to obtain panel time. (Broderick Dep. at 289-90, App. 45-46.)

Indeed, numerous physicians, whether from Ohio Heart or competing groups, never referred patients to The Christ Hospital to obtain panel time. Drs. Abbottsmith, Behrens, Broderick, Caples, Choo, Chung, Clarke, English, Forman, Fry (the Relator), Glassman, Hattemer, Henthorn, Hunter, Ivey, Jenike, Kereiakes, Murtaugh, Pelberg, Schneider, Snavely, Stewart-Dehner, Suresh, Thoresen, Toltzis, Waller, Whang, and the CEO for Comprehensive Cardiology Consultants have all attested to this fact.[1] Even doctors allegedly excluded by the so-called kickback scheme did not find the use of volume statistics an "inducement to send business to the hospital," but merely "a math problem that equitably divided time." (Snavely Dep. at 96, App. 234.)

The circumstantial evidence reinforces that defendants acted solely with patient-care concerns in mind. As for the use of volume statistics, it is sheer common sense that "physicians who routinely [made] greater use of the facility [were] expected to take on more responsibility and become more involved than a physician who seldom [used] the facility." *United States ex. rel Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 864 (C.D. Ill. 2003). Likewise, as to Ohio Heart in particular, because it had the most cardiologists at the hospital, it had no incentive

[1] (*See* Behrens Decl. ¶ 5, App. 975; Broderick Dep. at 272, App. 40; Caples Decl. ¶ 5, App. 979; Choo Decl. ¶ 5, App. 981; Chung Decl. ¶ 5, App. 983; Clarke Decl. ¶ 5, App. 985; English Decl. ¶ 5, App. 987; Forman Decl. ¶ 5, App. 989; Fry Dep. at 108, App. 94; Glassman Decl. ¶ 5, App. 991; Hattemer Dep. at 50-51, App. 128-29; Henthorn Dep. at 39, App. 153; Hunter Decl. ¶ 5, App. 993; Ivey Decl. ¶ 6, App. 995; Jenike Dep. at 18, App. 160; Kereiakes Decl. ¶ 5, App. 999; M. McDonald (First) Dep. at 41, App. 169; Murtaugh Decl. ¶ 5, App. 1001; Pelberg Decl. ¶ 5, App. 1003; Schneider Decl. ¶ 5, App. 1005; Snavely Dep. at 21, App. 231; Stewart-Dehner Decl. ¶ 5, App. 1007; Suresh Dep. at 37, App. 237; Thoresen Decl. ¶ 5, App. 1009; Toltzis Dep. at 129, App. 278; Whang Dep. at 18, 21, App. 307; Waller Decl. ¶ 5, App. 1013; Wietmarschen Dep. at 71, App. 330.)

to refer patients to obtain panel time because it would receive a substantial portion *no matter how it was allocated*. And often it took less. (*See* Dep. Ex. 147, App. 414.)

Second, the United States has failed to present sufficient evidence to show that the alleged Anti-Kickback Statute violation could create liability under the False Claims Act. For starters, the evidence now shows that defendants did not make an "objectively false" statement, a prerequisite under the False Claims Act. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). At most, the United States has illustrated "differences in interpretation growing out of a disputed legal question," which "are . . . not false." *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999). While this Court rejected defendants' motion-to-dismiss argument on the Anti-Kickback Statute's scope (R.95 at 11-18), new evidence proves that reasonable minds could differ on that question, especially since the United States has now admitted it did not provide specific guidance on the present or related topics. (United States' Admissions at 20, 35, App. 722, 737.)

That lack of guidance is not only a basis for rejecting the United States' newly minted legal theory, but is also not surprising given the lack of consensus on the issue. When the United States asked the health care community if medical-staff privileges, which share similarities to panel assignments, were "remuneration" under the Anti-Kickback Statute, it received arguments on both sides of the "disputed legal question." *Lamers*, 168 F.3d at 1018. Many hospitals indicated that the granting of privileges is *not* an "in cash" or "in kind" payment, and that any monetary benefit arises only from the third-party "payment made by the physician's patient or his/her insurer for professional services rendered." (Am. Hosp. Ass'n (AHA) Public Comments, at 2, App. 593.) That, too, describes panel-time allocations. Thus, to find an objective falsehood here, the Court has to conclude not only that the United States engaged in a meaningless exercise

when asking for public comments on the privileges question but also that the hospital community responded with an unreasonable answer.

Nor can the United States turn the alleged Anti-Kickback Statute violation into a "legally false claim." It cannot rely on the "implied certification" theory of liability because, as courts have recognized, the "Anti-Kickback Statute itself does not expressly state that a provider must comply with the statute in order to be paid." *United States ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00-cv-4863, 2003 U.S. Dist. LEXIS 27469, at *23 (E.D. Pa. Aug. 14, 2003). And the express certifications identified in the United States' complaint (R.53 at 10-12) fall short both because they do not "state that compliance [with the Anti-Kickback Statute] is a prerequisite to payment," *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1218 (10th Cir. 2008), and because they broadly certify compliance with "all regulations or statutes governing participation" in the health care program, *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 501 (S.D. Tex. 2003), *aff'd*, 111 Fed. App'x 296 (5th Cir. 2004).

The United States also cannot show that defendants "knowingly" submitted false claims. 31 U.S.C. § 3729(a). At most, defendants' agents viewed the panel-allocation method as falling within a legal "gray area," when it was brought to their attention. (Morneault Dep. at 124, App. 194.) And "where disputed legal issues arise from vague provisions or regulations, a [defendant's] decision to take advantage of a position can not result in his filing a 'knowingly' false claim." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 (5th Cir. 2003) (Jones, J., concurring). Finally, unlike with the Stark Law (which is not at issue), not all Anti-Kickback Statute violations are material. Rather, "'technical violations'" are routinely excused, meaning that a plaintiff must "prove the materiality of the [specific] violation." *United States ex rel.*

Sharp v. Consol. Med. Transp., Inc., No. 96 C 6502, 2001 WL 1035720, at *10 (N.D. Ill. Sept. 4, 2001). The United States, however, has presented no evidence on the point.

Third, at the least, defendants are entitled to summary judgment on many of the claims alleged in the complaint. To begin with, defendants cannot be liable for the period during which Medical Diagnostic Associates, Inc. (MDA), a billing entity for physicians, allocated panel time. MDA decided the manner in which to allocate panel separate from the hospital, and its physicians felt that they could "distribute [panel] how [they'd] like." (Broderick Dep. at 207, App. 32.) That belief was buttressed by the fact that MDA repeatedly told its lawyers about its allocation method and the lawyers never raised so much as a "peep" about it. (*Id.*)

In addition, the United States lacks sufficient evidence to present its far-reaching damages theory to the jury. For every claim the United States alleges is false, it must meet every element of the Anti-Kickback Statute. It has failed to do so for most claims. Among other things, many cardiologists, including Dr. Fry himself, did not even know how administrators assigned panel, proving that they were not offered it for referrals. (*See* Fry Dep. at 106, App. 92; Hattemer Dep. at 8-9, App. 117-18.) Similarly, many cardiologists did not value panel, and so those cardiologists were not offered the required "thing of value." (*See* Hattemer Dep. at 32, 70-71, App. 123, 131-32; Whang Dep. at 19-20, App. 307.) The United States, therefore, cannot seek as damages any claims for services rendered by these doctors.

As a final matter, the United States cannot proceed with its "reverse false claims" count. *See* 31 U.S.C. § 3729(a)(7). To do so, it must show that defendants made a false statement to conceal an "obligation to pay" it. *Id.* But where this "obligation arises if and only if a defendant makes a false statement or files a false claim . . . , an action under [this provision] will not lie." *Am. Textile Mfrs. Inst., Inc. v. The Limited, Inc.*, 190 F.3d 729, 734 (6th Cir. 1999). Because the

United States has asserted that defendants had an obligation to pay solely due to their purported false claims, its allegations run directly counter to controlling law.

STATEMENT OF THE FACTS

A. The Christ Hospital Utilized Heart Station Panels To Treat Cardiac Patients In A Timely, Quality Manner.

To best serve its cardiac patients, The Christ Hospital operated a "Heart Station" where patients could undergo noninvasive cardiac testing. The tests included electrocardiograms ("EKGs"), echocardiographs ("echos"), and stress tests ("GXTs"). (Wall Dep. at 15-18, App. 287-88.) Before a patient could be scheduled for a test, a physician would first have to order the test. (Tempel Dep. at 10, App. 243.) If the ordering physician did not identify a cardiologist to read it, the responsibility fell on the hospital to ensure that a qualified cardiologist was available to read the test in a timely manner. (*Id.* at 24, App. 252.) To fulfill that duty, the hospital established panels for EKGs (EKG panel) and stress tests and echos (GXT panel). Qualified cardiologists staffed the Heart Station to perform and/or read these tests during their panel times. (*See* Croushore Dep. at 68, App. 64.)

To cover the costs it incurred for this patient care, the hospital typically billed patient insurance. (Tempel Dep. at 81, App. 265.) Cardiologists also billed insurance for their professional fees. (*Id.*) While critical for patient care, the tests themselves were not highly paid. Indeed, cardiologists had "talked about" demanding payment for the panel commitment "for a long time," but never forced the hospital to pay. (Toltzis Dep. at 215, App. 283.) In 1989, cardiologists formed MDA to collectively bill for all their Heart Station services, which lowered their administrative costs. (Abbottsmith Dep. at 12-13, App. 2-3.)

Panel times were assigned annually because cardiologists needed to know, months in advance, when they could schedule patients for office visits. (Croushore at 25, App. 60.) The

GXT panel was divided into ten morning and afternoon slots, and cardiologists covered their assigned slots each week for the year. (Wall Dep. at 22, 47, App. 289, 294.) The EKG panel was divided by weeks, and cardiologists read EKGs twice daily during their assigned weeks. (Wietholter Dep. in *UIMA v. MDA* at 8-9, App. 311-12; Toltzis Dep. at 24, App. 271.)

B. In The Late 1980s, Quality Concerns Compelled Hospital Administrators To Change The Manner In Which Cardiologists Were Allocated Panel.

Before the late 1980s, cardiologists assigned panel times themselves. (Tempel Dep. at 14, App. 245.) Many cardiologists, however, frequently missed their scheduled times, delaying diagnostic testing and interpretation. (*Id.* at 24, App. 252.) Hospital administrators understandably became concerned about the patient-care, "ethical," and "malpractice issues" raised by cardiologist absenteeism. (*Id.*)

Around 1987, these administrators, including CFO Phil Tempel, developed a new method to allocate panel time. (*Id.* at 13, App. 244.) Chief among their concerns was "the failure to appear" by cardiologists, which they understood was "associated with [cardiologists] who actually didn't practice [at the hospital] very much." (*Id.* at 25, App. 253.) Given the problem's "cause," they felt the remedy "[lent] itself to" an approach with a "driving principle" that cardiologists who staffed panel "had to be there at the hospital." (*Id.* at 20, 25, 67, App. 249, 253, 263.) In other words, "because the physicians who were using the services of the hospital were at the hospital, physically at the hospital," administrators felt these physicians "would be more likely to be available to read EKGs or to be available to do the stress testing." (Croushore Dep. at 15, App. 57.) In contrast, "patients were put at risk by physicians who had privileges but weren't present." (Tempel Dep. at 52, App. 257.)

Tempel identified the statistics that would "indicate how frequently a practitioner was present in [the hospital's] facilities." (*Id.* at 29, App. 254.) He developed "a statistical

calculation which reflected the inpatient volume of service, the outpatient volume of service, and had . . . an extra provision that reflected physicians who volunteered [to train] internal medicine residents." (*Id.* at 15, App. 246.) These numbers, he believed, were an objective proxy for presence because the "physicians who actually came to Christ Hospital had a higher statistical profile than a physician who did not." (*Id.* at 78, App. 264.) In developing the allocations, Tempel looked to "the prior year's information." (*Id.* at 21, App. 250.) The allocations were then provided to Dr. Charles Abbottsmith, Chief of Cardiology, who coordinated with the cardiologists to prepare the annual schedule. (Abbottsmith Dep. in *UIMA v. MDA* at 9-10, App. 9-10.) After Tempel established this system, the absentee problem largely subsided. (Tempel Dep. at 34, App. 255.)

C. Throughout The 1990s, Heart Station Panel Coverage Informally Evolved.

The Heart Station panels evolved in the 1990s from their original inception. Large cardiology practicing groups began to emerge such that "[e]very hospital in the city" had "a dominant cardiology group." (Wietmarschen Dep. at 88, App. 331.) With respect to The Christ Hospital, Ohio Heart, which formed in 1995 with a total of fifteen to twenty cardiologists, (Toltzis Dep. at 27-28, App. 272-73), became the largest group practicing there. Its members pooled their panel, which led to Ohio Heart having the majority (Wall Dep. in *UIMA v. MDA* at 19-20, App. 299-300), just as other large groups covered the majority at other hospitals (Wietmarschen Dep. at 88-89, App. 331).

For his part, Dr. Fry added partners in 1996. (Dep. Ex. 51, App. 387.) He asked Claus Von Zychlin, the hospital's Senior Executive Officer (SEO), to place his new partners on the panels. (*Id.*) Unaware of how panel was assigned, Von Zychlin asked Susan Wietholter, Vice President of Nursing, to look into the issue. After some research, Wietholter wrote Von Zychlin to detail her findings. (Dep. Ex. 2, App. 334.) For the GXT panel, Wietholter's research

revealed that administrators had stopped using Tempel's method. Instead, the same trusted doctors were assigned the same slots each year. (Wietholter Dep. in *UIMA v. MDA* at 7-8, App. 310-11; Dep. Ex. 2 at 1, App. 334.) For the EKG panel, the hospital continued to rely upon Tempel's "simple mathematical calculation," (Tempel Dep. at 18, App. 248), which, for EKG panel, was still viewed as best for patient-care purposes. (Dep. Ex. 2 at 1-2, App. 334-35.) In her memo, however, Wietholter suggested that Tempel's method "potentially could put [the hospital] at risk legally," and that Fry had indicated, without any specificity, that the processes "could be legally challenged." (*Id.*)

Von Zychlin did not believe Fry's accusations had anything to do with compliance issues. (Von Zychlin Decl. ¶ 5, App. 1012.) To him, the manner in which the hospital staffed panels seemed appropriate given the standard practice of looking to volume statistics for similar decisions. (*Id.* ¶ 4, App. 1011.) Tempel, by comparison, had believed his allocation method was a "legal process," and spoke with an attorney about panel in the 1990s. (Tempel Dep. at 43, App. 256.) In response to Fry's letter, Von Zychlin said that the schedules were made annually and that no changes could be made mid-year. (Dep. Ex. 3, App. 336.)

By the late 1990s, the EKG allocation had become a "ministerial function" undertaken by low level administrators (Croushore Dep. at 12, App. 54), with the annual math problem delegated to an administrative intern. (*See* M. McDonald (Second) Dep. at 11, App. 174; Wietholter Dep. in *UIMA v. MDA* at 9, App. 312.) And instead of Dr. Abbottsmith, Tina Wall, the Heart Station manager, began coordinating with cardiologists to create the annual schedule. (Wall Dep. at 37-40, App. 291-92.)

D. By 1999, Hospital Administrators Faced Both A Lack Of Adequate Coverage And Physician Concerns Regarding Panel Patient Services.

By 1999, panel changes became necessary. The GXT panel had become backlogged, so much so that the hospital "was having trouble covering the tests that [it] needed to get done." (Wall Dep. at 44, App. 293.) As a result, administrators split that panel into two, a GXT Panel and an Echo Panel (*id.* at 47, App. 294), which resulted in many GXT slots remaining open. (Wall Dep. in *UIMA v. MDA* at 9, App. 298.) By November 1999, administrators were "begging the various physicians to please cover the open slots."[2] Many refused as "[i]t wasn't worth their time to be there." (Wietmarschen Dep. at 31, App. 325.) These cardiologists included Dr. Fry. (Fry Dep. at 101-02; 121-22, App. 88-89, 100-01.)

Facing these challenges, the hospital convinced cardiologists to cover vacant slots on a piecemeal basis. Some, however, found the panel service to be an "extreme hardship." (Dep. Ex. 292 at 2, App. 585.) Ohio Heart doctors eventually agreed to cover the open slots. (Wall Dep. in *UIMA v. MDA* at 21, App. 301.)

By 1999, a decade had passed since Tempel had adopted his method, and most cardiologists, including Dr. Fry, did not know how administrators allocated panels.[3] Nevertheless, Fry, who had opted not to take additional GXT panel time, began to complain that Ohio Heart had the majority of times. (Fry Dep. at 105, App. 91.) One of those complaints came during an August 1999 meeting with Dr. Mike Jennings, Chair of the Internal Medicine Department. (Fry Dep. at 131, App. 103; Dep. Ex. 90 at 3-4, App. 761-62.) Fry claims that, during that meeting, Jennings stated that he had attended a meeting in which "lawyers had

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[2] (Croushore Dep. at 46, App. 62; *see, e.g.*, Dep. Ex. 4 at 3, App. 341; Dep. Ex. 57, App. 390; Dep. Ex. 167, App. 424; Dep. Ex. 280, App. 582; Dep. Ex. 291, App. 583.)

[3] (*See, e.g.*, Fry Dep. at 106, App. 92; Hattemer Dep. at 8-9, App. 117-18; Whang Dep. at 20-21, App. 307; Wietmarschen Dep. at 29-30, 65-66, App. 324-25, 328-29.)

advised administrators of The Christ Hospital that the system of allocation of work in the heart station was illegal." (Fry Dep. at 131, App. 103.) Jennings unequivocally denies this statement. (Jennings Decl. at ¶ 3, App. 997.) Rather, he remembers telling Fry that the hospital planned to review all hospital panels. (*Id.*)

Fry's complaints continued. In October 1999, he held a meeting with administrators Dick Seim (the new SEO) and Wietholter as well as non-Ohio Heart cardiologists. (Fry Dep. at 103, App. 90.) No cardiologist at the meeting knew the manner in which the hospital allocated panel. (*Id.* at 106, App. 92.) Seim and Wietholter likewise indicated they did not know. (*Id.* at 109, App. 95.) Seim, who had only been SEO for less than a year, had "no reason to be delving into that level of detail." (Seim Dep. at 10, 26, App. 198, 201.) Wietholter, moreover, did not recall her research or the issue from years earlier. (S. McDonald Dep. at 13, 22-23, App. 180, 183-84.) At the meeting, Fry alleged to Seim that the current system was illegal, although he did not explain why. (Fry. Dep. at 132, App. 104.)

Going forward, Seim investigated the panel processes because the uncertainty created "a fairness issue that the physicians deserved to have clarified." (Seim Dep. at 29, App. 202.) Although he had hoped to rely on his staff for historical perspective, the intern who allocated EKG panel for 1999 had since left. (M. McDonald (Second) Dep. at 10-11, App. 173-74.) With respect to the GXT and Echo Panels, Wall indicated that she carried over the prior year's schedule and filled in gaps as best she could. (Seim Dep. at 52-53, App. 205-06.) That said, "[n]one of [his staff] knew exactly how the panel formula worked or what the panel formula was." (M. McDonald (Second) Dep. at 11, App. 174.) And conversations with cardiologists were no more revealing. Seim took notes from these meetings that panels had been historically linked to volume, the approach he assumed Fry was alleging as illegal, but no one knew the

current method. (Seim Dep. at 43, 55, App. 204, 206; Dep. Ex. 5 at 2, 13, App. 354, 365.) Seim, in sum, could not find a conclusive answer as to historical or present allocation methods. (Seim Dep. at 20, App. 199.) Given the continued uncertainty, he decided to adopt a new method.

With 1999 nearing an end, however, the hospital needed to determine the next year's allocations to allow cardiologists to set their schedules. (*Id.* at 202, App. 219.) For that reason, Seim gave each group the same number of EKG weeks they had in 1999. (Seim Dep. at 202-03, App. 219-220; M. McDonald (Second) Dep. at 12, App. 175.) As described above, the other panels were allocated in a similar way. Seim carried over these numbers on the understanding that the hospital would develop a new method for 2001. (Seim Dep. at 202, App. 219.)

Seim saw the uncertainty as a fairness issue, not a legal one. He did not believe the current process could be illegal because none could define it. (Seim Dep. at 28-29, App. 201-02.) And since Seim had decided to change methods, he was more concerned about the "legality of a process that [the hospital] would be going to." (*Id.* at 23-24, App. 200.) In December 1999, despite Seim's efforts, Fry again made general illegality accusations. (Dep. Ex. 8, App. 372; Dep. Ex. 10 at 1-2, App. 377-78; Dep. Ex. 108 at 1, App. 409.) Because Fry was "incessant with the use of the word legal," Seim thought it was simply a self-serving statement to support one of his many complaints. (Seim Dep. at 37, App. 203; *see* 10/13/99 Fry Letter to Seim, App. 753; 10/16/99 Fry Letter to Seim, App. 755; 03/07/00 Fry Letter to Wall, App. 681; 06/12/01 Kuhn Letter to Jennings, App. 751.) For his part, Dr. Jennings did eventually meet with administrators and a lawyer about panels. (Jennings Decl. at ¶ 4, App. 997.)

E. In 2000, Hospital Administrators Proposed Outsourcing Panel Duties.

In 2000, Seim, with "[f]airness [as] [his] overriding concern," worked to develop a uniformly accepted method for panel allocation. (Seim Dep. at 75, App. 208.) In doing so, he met with doctors numerous times. (*Id.* at 70-71, App. 203-04; *see* Dep. Ex. 11 at 1-2, App. 379-

80; Dep. Ex. 71, App. 406; Dep. Ex. 62, App. 391.) He also requested a literature review, asked for national research, and investigated local practices. (Seim Dep. at 42-43, App. 204.) The results revealed no "industry standard." (*Id.*) Ultimately, he decided to propose a "Request for Proposal" (RFP) in which the hospital would outsource panel responsibilities to a third party. (*Id.* at 69, App. 207.) This idea originated from an outsourcing of the hospital's Vascular Lab Panel. (*Id.* at 24, App. 200; *see* Dep. Ex. 158, App. 416.) Seim believed that the RFP also responded to the cardiologists' desire to control the process. (Seim Dep. at 157, App. 216.) A legal review was also undertaken. (*Id.* at 24, App. 200.)

When Seim introduced the idea in April 2000, he received "pretty strong expressions of enthusiasm for this approach from the physicians uniformly." (*Id.* at 100, App. 209.) Seim thus sent out a formal RFP. (Dep. Ex. 65, App. 397.) The RFP did not compel the third party to allocate panel in any particular manner. It indicated only that participating physicians needed to be members of the medical staff, to be appropriately credentialed, and to treat cardiac disease as a significant part of their practice. (*Id.* at 1, App. 397.) The RFP also placed emphasis on including all interested cardiologists. (*Id.* at 3, App. 399.)

F. MDA Physicians Allocated Panel Time From 2001 To 2004.

In response to the RFP, Dr. Fry proposed that MDA, the physician billing company, "be the contracting group." (04/20/00 Fry Letter, App. 684.) Cardiologists universally agreed.[4] While Dr. Fry initially took the lead in proposing a response, (Fry Dep. at 117-18, App. 96-97), he eventually resigned his position for personal reasons. (*See* Dep. Ex. 64, App. 396; Dep. Ex. 90 at 1, App. 759.) When Fry held a leadership role, the cardiologists suggested that Ohio Heart

[4] (*See* Abbottsmith Dep. at 36, App. 4; Broderick Dep. at 63-64, App. 19-20; Fry Dep. at 130, App. 102; Jenike Dep. at 37, App. 162.)

take seventy percent and that non-Ohio Heart cardiologists divvy up the rest. (Fry Dep. at 118-20, App. 97-99.)

At later meetings, MDA doctors decided upon an allocation method. (Abbottsmith Dep. at 44, App. 5; Broderick Dep. at 153, 266, App. 27, 39; Hattemer Dep. at 30, App. 121; Seim Dep. at 168, App. 217; Wietholter Dep. in *UIMA v. MDA* at 25, App. 313.) The physicians did not know the specific manner any hospital divided panel. (Broderick Dep. at 171, App. 28.) There was, however, "some obvious volume or some sort of credentialing criteria in that it was the people who were at those hospitals and busy that got the panel assigned to them. And if they had little or no presence at the hospital, then they typically weren't asked to participate." (*Id.* at 171-72, App. 28-29; *see* Desai Dep. at 38-39, App. 78.) Cardiologists thus decided that they "needed some formula" to measure hospital participation. (Abbottsmith Dep. at 44, App. 5.)

To respond to the RFP, physicians asked Wietholter for data on cardiologists. They asked for gross charges for cardiac services and the number of referrals to cardiac surgeons. (*See* Dep. Ex. 16, App. 381; S. McDonald Dep. at 46, App. 186; Broderick Dep. at 123-24, 263, App. 25-26, 38.) Wietholter obtained the information from The Health Alliance's "decision support," which converted the gross charges into Medicare "DRG" format. (S. McDonald Dep. at 46, App. 186; Broderick Dep. at 263, App. 38.) She knew they were going to use the data "in development of the panel, but [she did not] know in what way." (Wietholter Dep. in *UIMA v. MDA* at 27, App. 315.) She figured MDA wanted to ensure panel would be staffed by "physicians that [were] practicing at the hospital on a regular basis . . . and [were] present at the hospital" to ensure patient coverage. (S. McDonald Dep. at 39, App. 185.) Seim was of the same mind. (Seim Dep. at 165-66, App. 217.)

MDA responded to the RFP in September 2000. MDA's business manager, Dr. Broderick, an Ohio Heart cardiologist, drafted the response. (Broderick Dep. at 153, App. 27.) To determine "the depth of participation in hospital activities," the response indicated that the cardiologists relied upon "consultations, admissions, cardiac surgery referrals, invasive and non-invasive procedures performed; past and on-going service to the hospital in support of existing panel structures; and participation in section governance activities and medical education." (Dep. Ex. 66 at 1, App. 400.) Its allocations decreased Ohio Heart's EKG time by seven weeks and its GXT/Echo time by two slots. (*See* Dep. Ex. 66 at 2-3, App. 401-02; Dep. Ex. 4 at 3-4, App. 341-42.)

In December 2000, administrators met with MDA cardiologists to agree on the contract. (*See* Dep. Ex. 69 at 1, App. 404.) Once signed, MDA held the exclusive right to allocate panel in any manner it chose until 2002. A subsequent addendum gave MDA "the exclusive right to distribute both EKG and reading assignments" through 2004. (Dep. Ex. 228 at 1, App. 451.)

Each year that MDA allocated panel, Broderick, as its business manager, asked Wietholter for varying forms of volume data, often making multiple requests of her. (*See* Dep. Ex. 18, App. 384; Wietholter Dep. in *UIMA v. MDA* at 26-29, App. 314-17.) Each Fall, a small MDA group held a handful of meetings to decide upon the next year's allocations. (*See* Dep. Ex. 129, App. 411; Dep. Ex. 177, App. 425; Dep. Ex. 183, App. 428.) Prior to the meetings, Broderick added up the percentages of the cardiologists' volumes to facilitate divvying up the work. (Broderick Dep. at 94, App. 24.) While distribution of the EKG panel more closely paralleled volume percentages, Ohio Heart took significantly less GXT time than the statistics would indicate. (*Id.* at 77-79, App. 21-23.) The group informally considered other factors such as assisting with panel in times of short staffing. (*Id.*; *see* Dep. Ex. 129 at 3, App. 413.)

During the last year MDA allocated panel, the United States had started investigating this case. It asked an MDA doctor, Robert Toltzis, secretly to wear a wire to MDA meetings in October 2003. (Toltzis Dep. at 124, App. 274; Dep. Exs. 257-58, App. 826-27.) As the transcripts of those meetings confirmed, doctors negotiated and allocated panel themselves without hospital involvement. (Broderick Dep. at 308-10, App. 48-50; *see* Dep Ex. 247 at 7-8, App. 483; Dep. Ex. 248 at 6, App. 542.) These transcribed meetings were typical of all MDA meetings to allocate panel. (Toltzis Dep. at 125-26, App. 275-76.)

During this time, Dr. Broderick relied upon the Schwartz, Manes & Ruby law firm "to take care of whatever things that [MDA] needed from a compliance standpoint." (Broderick Dep. at 204, App. 31.) As a physician, Broderick did not "know every nuance of the law," and expected lawyers to raise legal concerns from the facts he communicated. (*Id.* at 213-15, App. 33-35.) In that respect, Broderick repeatedly disclosed the manner in which MDA allocated panel. (*Id.*) In an email, he told a lawyer that MDA based panel allocation upon "volume brought to the hospital such that physicians who have a strong commitment to and presence at the hospital are rewarded." (Dep. Ex. 236, App. 476.) The lawyer raised no concerns. (Broderick Dep. at 214, App. 34.) In addition, University Internal Medicine Associates ("UIMA") sued MDA over panel time. In that litigation, Broderick told MDA lawyers the manner that panel was allocated. (*See* Dep. Ex. 234, at 3, 8; App. 469, 474; Broderick Dep. at 274-76, App. 41-43.) Counsel raised no concerns. Broderick instead recalls lawyers indicating that physicians could "distribute [panel] how [they'd] like" because MDA was "an independent group" separate from the hospital. (Broderick Dep. at 207, App. 32.)

Hospital administrators felt the same way. MDA's use of volumes did not concern Seim because the hospital "had gone through a process that [he] thought was fair in terms of selecting

another group to do the panel assignments" so any panel issues were MDA's, not the hospital's. (Seim Dep. in *UIMA v. MDA* at 61, App. 224; Hanover Dep. at 66-68, App. 111-13.)

G. In Late 2003, Administrators Decided To Retake The Responsibility To Allocate Panel Time Once The MDA Contract Expired.

By late 2003, Seim and Wietholter had left the hospital (Seim Dep. at 11, App. 198; S. McDonald Dep. at 8, App. 179), and were replaced by Susan Croushore (the new SEO) and Debbie Hayes (the new Vice President of Nursing). That year, Dr. Broderick asked Hayes for the data Wietholter previously provided. (Hayes Dep. at 68, App. 137.) Hayes, new to the issue, was concerned about providing it because physicians did not generally view other physicians' statistics. (*Id.* at 94-95, App. 138-39.) She spoke with Jeff Morneault, head of The Health Alliance's Cardiovascular Service Line, who asked for compliance help because he was also new to the panel issue. (Morneault Dep. at 88-89, App. 192.)

Likewise, around this time, Dr. Charles Hattemer replaced Dr. Abbottsmith as Chief of Cardiology. (Hattemer Dep. at 5, App. 116.) In carrying out his new responsibility, he became concerned about MDA because he thought the use of volume statistics may raise legal issues and because doctors had complained about MDA's high overhead and lack of adequate reimbursement. (*Id.* at 28-29, App. 119-20.) Accordingly, Hattemer met with the new administrators to discuss the MDA relationship. The administrators indicated that the MDA relationship had satisfied the patient-care needs of the panel as "all the days were covered" and testing was timely provided. (*Id.* at 35, App. 124.) Nonetheless, given the discontent, they agreed to end the relationship. (*Id.* at 35-37, App. 124-26.)

Having decided to change the method of panel assignments, administrators nonetheless faced practical restraints. For one, they could not change quickly enough for 2004, given doctors' schedules and resulting patient-care concerns. (*Id.*) For another, they were afraid that if

they unilaterally ended the MDA relationship, which was contractually set through 2004, MDA could sue for breach of contract. (Croushore Dep. at 162, App. 70.) Accordingly, the new method was first utilized in 2005.

Beginning in 2005, the administrators and Dr. Hattemer initiated a new process. Every cardiologist had "an opportunity to express an interest in doing panel" and those interested who met quality criteria were offered equal time. (Hattemer Dep. at 30-31, App. 121-22.) When the new method was adopted, allocations were "very similar to what had been provided under MDA and even prior to MDA as far as the amount of coverage." (Croushore Dep. at 163, App. 71; *see* Toltzis Dep. at 168-69, App. 279-80.) In 2005, Ohio Heart cardiologists were offered seventy percent and took fifty. (Dep. Ex. 147, App. 414.)

ARGUMENT

Despite the tens of thousands of documents requested and the dozens of depositions taken, the United States has not produced enough evidence to survive summary judgment. Summary judgment is proper where "there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). To overcome such a motion, "the nonmoving party may not rest on the mere allegations in the pleadings." *McKenzie v. BellSouth Telecomms., Inc.*, 219 F.3d 508, 512 (6th Cir. 2000). Instead, it must "make a showing sufficient to establish the existence of [all] element[s] essential to that party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

Under these standards, the Court should grant summary judgment to defendants. *First*, the United States lacks evidence to show that defendants, in providing needed care for patients, maintained the criminal intent necessary to violate the Anti-Kickback Statute. *Second*, all counts also fail because the United States has not created a jury issue over whether an alleged violation of the Anti-Kickback Statute could support liability under the False Claims Act. *Third*, at least, the Court should grant summary judgment to defendants on a portion of the alleged false claims.

I. DEFENDANTS DID NOT HARBOR THE CRIMINAL INTENT NECESSARY FOR A VIOLATION OF THE ANTI-KICKBACK STATUTE, REQUIRING SUMMARY JUDGMENT ON ALL COUNTS.

A. The Anti-Kickback Statute Requires The United States To Prove That An Agent Of Each Defendant Acted With A Specific Criminal Intent.

The Anti-Kickback Statute makes it a felony to knowingly (1) "offer[] or pay[]" remuneration in cash or in kind "*to induce*" referrals of federally insured patients or (2) "solicit[] or receive[]" this remuneration "*in return for*" these referrals. 42 U.S.C. § 1320a–7b(b)(1)-(2) (emphasis added). Notably, "[a]s is evident from [this] text, [the] statute makes intent a key element," *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 683 (W.D. Ky. 2008). Accordingly, "evidence of a corrupt intent is necessary to prove a violation." *Feldstein v. Nash Cmty. Health Servs., Inc.*, 51 F. Supp. 2d 673, 681 (E.D.N.C. 1999) (internal quotation marks omitted); *see McDonnell v. Cardiothoracic & Vascular Surgical Assocs., Inc.*, No. C2-03-79, 2004 WL 3733402, at *8 (S.D. Ohio July 28, 2004) ("The anti-kickback statute . . . establishes an intent-based criminal prohibition . . . .") (internal quotation marks omitted).

The criminal intent that the United States must prove depends on whether the defendant is alleged to have "offered or paid" remuneration, on the one hand, or "solicited or received" remuneration, on the other. If the defendant is alleged to have "offered or paid" remuneration, as the United States alleges was done by The Christ Hospital and The Health Alliance, the United States must prove that the defendant did so with the specific intent "to induce" referrals of federally insured patients. 42 U.S.C. § 1320a-7b(b)(2); *see Feldstein*, 51 F. Supp. 2d at 681 (noting that "[t]he statute is aimed at the inducement factor") (internal quotation marks omitted). Stated another way, the defendant must have the "intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) (internal quotation marks omitted). The

Christ Hospital and The Health Alliance cannot be found liable, by contrast, if they merely "hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes." *McClatchey*, 217 F.3d at 834.

Separately, when a defendant is alleged to have "solicited or received" remuneration, as the United States alleges occurred with respect to Ohio Heart, the United States must prove that the defendant did so with the specific intent that the remuneration be "in return for" referrals. 42 U.S.C. § 1320a-7b(b)(1). "To solicit or receive remuneration in return for referrals means to solicit or receive remuneration with intent to allow the remuneration to influence the reason and judgment behind one's patient referral decisions." *LaHue*, 261 F.3d at 1002 n.11 & 1004 (internal quotation marks omitted). As a result, the United States must show that Ohio Heart specifically intended the alleged payment to influence its referral decisions. If, by contrast, it referred patients solely "because of a belief that the place to which the patients [were] to be referred [was] attractive," it cannot be liable. *Id.* at 1007-08 (internal quotation marks omitted).

In either situation, the defendant must also have acted "willfully." 42 U.S.C. § 1320a–7b(b)(1)-(2). In its prior order, this Court disagreed with decisions holding that this element requires the United States to present evidence that defendants actually knew they were acting unlawfully. *See United States v. Starks*, 157 F.3d 833, 839 & n.8 (11th Cir. 1998); *Hanlester*, 51 F.3d at 1400. Nonetheless, under that order, this element still requires the United States to prove that defendants acted with a "purpose to commit a wrongful act." (R.95 at 18 (internal quotation marks omitted).)

Finally, when applying these intent elements to corporate defendants like those here, the United States must prove that a specific corporate employee harbored the corrupt intent while acting in the scope of employment and for the benefit of the employer. *See Dana Corp. v. Blue*

Cross & Blue Shield Mut. of Northern Ohio, 900 F.2d 882, 886 n.2 (6th Cir. 1990) (noting for a similar crime that "[a] specific corporate employee must be found to have the intent"). This requirement to prove criminal intent by a specific agent is widely understood. *See, e.g.*, *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) ("To prove liability against a corporation, of course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation."); *Saba v. Compagnie Nationale Air France*, 78 F.3d 664, 670 n.6 (D.C. Cir. 1996) ("[C]orporate knowledge of certain facts [can be] accumulated from the knowledge of various individuals, but the proscribed intent (willfulness) depend[s] on the wrongful intent of specific employees.").

B. The United States Has Failed To Raise A Genuine Issue Of Material Fact As To Whether Agents Of The Christ Hospital, The Health Alliance, And Ohio Heart Acted With The Necessary Criminal Intent.

The United States' failure to satisfy the Anti-Kickback Statute's intent element dooms its complaint. Courts disagree whether this illegal motivation must be a "primary purpose" for a defendant's actions, as defendants' here contend, or simply "one purpose." *See Solinger*, 543 F. Supp. 2d at 697. Defendants believe that, as the *Solinger* court noted, the "one purpose" test could result in the Anti-Kickback Statute criminalizing a wide array of appropriate and important patient-care conduct. *See id.* Indeed, a hospital's very existence is designed to encourage physician referrals. (*See* Tempel Dep. at 83-84, App. 266-67.) But the Court need not decide this legal debate for purposes of this summary-judgment motion. Even if the lower standard applies, which defendants dispute, the United States lacks evidence to show that their agents acted even partially with an illegal intent.

1. Defendants' agents acted for legitimate reasons when assigning or staffing panel, not with any purpose to commit a wrongful act.

Though intent is generally a fact question, "[a] party against whom summary judgment is sought is not entitled to a trial simply because he has asserted a cause of action to which state of mind is a material element." *Stepanischen v. Merchants Despatch Transp. Corp.*, 722 F.2d 922, 929 (1st Cir. 1983). To the contrary, "'[t]he summary judgment rule would be rendered sterile . . . if the mere incantation of intent or state of mind would operate as a talisman to defeat an otherwise valid motion.'" *Ennis v. Nat'l Assoc. of Bus. & Educ. Radio, Inc.*, 53 F.3d 55, 62 (4th Cir. 1995) (quoting *Meiri v. Dacon*, 759 F.2d 989, 998 (2d Cir. 1985)). In the employment-law context, for example, courts routinely grant summary judgment where an employee fails to present sufficient evidence that the expressed intent for an employer's actions was merely a pretext for an illegal intent to discriminate based on a protected class. *See Chen v. Dow Chem. Co.*, 580 F.3d 394, 400 (6th Cir. 2009). This framework provides similar guidance for assessing a defendant's lack of criminal intent under the Anti-Kickback Statute. *See Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 682 (N.D. Ill. 2006).

Here, evidence of criminal intent is entirely lacking. Defendants' agents consistently indicated that they acted for good-faith reasons. Agents of The Christ Hospital and The Health Alliance all explained that Heart Station panel time—the alleged remuneration—was "designed wholly for other purposes" than to induce referrals, namely, assuring proper patient care. *McClatchey*, 217 F.3d at 834. Indeed, all administrators indicated that their singular purpose in making this necessary offer of panel was to ensure "that [it] was covered" in a fair, efficient, and quality manner. (Wietholter Dep. in *UIMA v. MDA* at 29, App. 317; *see* Seim Dep. at 157-58, 193, App. 216, 218; Tempel Dep. at 23-25, App. 251-53; Wall Dep. in *UIMA v. MDA* at 32, App. 302.) Notably, unlike in a case where the alleged remuneration is money, it is undisputed

that administrators were *required* to offer cardiologists panel. If, in other words, cardiologists did not take panel, the hospital could not operate the Heart Station and patients could not receive care.

Likewise, Ohio Heart cardiologists treated patients at The Christ Hospital because it offered "great equipment" and "superb nursing care" and because they "fel[t] like [their] patients [were] getting the best care" and had "the best chance of doing well" there. (Broderick Dep. at 289-90, App. 45-46.) Indeed, the hospital was Ohio Heart's principal location, and some Ohio Heart cardiologists practiced there exclusively. (*See* Toltzis Dep. at 129, App. 278.) None referred patients to the hospital for the criminal purpose of soliciting or receiving panel time.[5]

2. The United States lacks sufficient evidence to establish that defendants' agents acted not simply for these legitimate reasons, but also with an illegal criminal intent.

To create a jury question, the United States must show that, at all relevant times, an employee of each defendant was motivated not only by these expressed reasons but also by illegal ones. In particular, it must present evidence that a specific employee of The Christ Hospital or The Health Alliance offered cardiologists panel not only to ensure adequate coverage but also with the criminal intent to induce referrals. It must also present evidence that a specific cardiologist from Ohio Heart referred patients to the hospital not simply because of its quality but also with the specific intent to obtain panel time. In numerous ways, the record reveals otherwise.

[5] (*See* Behrens Decl. ¶ 5, App. 975; Broderick Dep. at 246, App. 36; Caples Decl. ¶ 5, App. 979; Choo Decl. ¶ 5, App. 981; Chung Decl. ¶ 5, App. 983; Clarke Decl. ¶ 5, App. 985; English Decl. ¶ 5, App. 987; Forman Decl. ¶ 5, App. 989; Glassman Decl. ¶ 5, App. 991; Hattemer Dep. at 50-52, App. 128-30; Hunter Decl. ¶ 5, App. 993; Ivey Decl. ¶ 6, App. 995; Kereiakes Decl. ¶ 5, App. 999; Mitts Decl. ¶ 4, App. 1015; Murtaugh Decl. ¶ 5, App. 1001; Pelberg Decl. ¶ 5, App. 1003; Schneider Decl. ¶ 5, App. 1005; Smith Decl. ¶ 4, App. 1017; Stewart-Dehner Decl. ¶ 5, App. 1007; Thoresen Decl. ¶ 5, App. 1009; Toltzis Dep. at 129, App. 278; Whang Dep. at 14-17, App. 306; Waller Decl. ¶ 5, App. 1013.)

First, defendants could (and did) have common-sense, legal reasons for relying upon referral or volume numbers when allocating panel time. As a legal matter, courts have recognized that volume measures for staffing decisions are "nothing more than a customary way of linking a physician's administrative and participatory responsibilities to his/her usage of the facility." *Perales*, 243 F. Supp. 2d at 864. In other words, "physicians who routinely make greater use of the facility are expected to take on more responsibility and become more involved than a physician who seldom uses the facility." *Id.*

And, as a factual matter, that is exactly what hospital administrators intended here. As Phil Tempel indicated, administrators began looking at volume metrics because cardiologists who "didn't practice there very much" were failing to show up for panel. (Tempel Dep. at 25, App. 253.) The volume-based method remedied this problem by ensuring that cardiologists who staffed panel "had to be there at the hospital." (*Id.* at 20, App. 249.) Common sense indicates that those physicians regularly working at the hospital are more likely to timely arrive than physicians who simply "came in and read" and then "disappeared." (Suresh Dep. at 60, App. 238.) Indeed, as one third-party cardiologist put it, "[t]he more time you spend there the easier it is to . . . find time to read the panels." (Jenike Dep. at 13, App. 159.)

Administrators gave volume statistics to MDA each year for similar reasons. Knowing that "there had been issues related to timeliness and availability" for panels, they believed that MDA's use of volume data would ensure that panel was staffed by "physicians that [were] practicing at the hospital on a regular basis . . . and [were] present at the hospital." (S. McDonald Dep. at 39, App. 185.) The administrators, in other words, knew that "volume information" was "very appropriately used in a number of settings," and so they did not find it unusual "that volume information was part of what MDA was looking at independent of the

Christ Hospital." (Seim Dep. at 166, App. 217.) Even when administration again turned over, the new administrators felt that the MDA relationship was a "good solution" to ensure timely panel coverage. (Croushore Dep. at 146, App. 67; *see* Hattemer Dep. at 35, App. 124.)

And while Dr. Broderick, acting as MDA's business manager, indicated to MDA lawyers and in the UIMA lawsuit against MDA that MDA used volume statistics in part "to reward" cardiologists for their presence at the hospital, (*see* Broderick Dep. at 172-73, App. 29-30; Dep. Ex. 236, App. 476), his statements are of little significance. For one thing, it is undisputed that Dr. Broderick, as MDA's business manager, was not acting as an agent of The Christ Hospital or The Health Alliance, and his intent cannot be imputed to them. *See Dana Corp.*, 900 F.2d at 886 n.2 (noting that "[a] specific corporate employee must be found to have the intent"). For another, panel time would only be a "reward" for practicing at The Christ Hospital in the same sense that the hospital's state-of-the-art equipment and quality staff are also "rewards" for practicing there. (Tempel Dep. at 83-84, App. 266-67.) But these physician benefits all result from the hospital's duty to treat patients and cannot create the necessary intent under the Anti-Kickback Statute. (*Cf.* Horty, Springer & Mattern Public Comments at 6, App. 621.) If they could, the hospital would have to stop serving patients to avoid liability. The hospital exists for physicians to treat patients there, and its mere existence cannot itself establish Anti-Kickback Statute liability.

Second, most physicians did not know how administrators assigned panel time.[6] Had those administrators intended to induce referrals by offering panel time, they would have

[6] (*See* Behrens Decl. ¶ 4, App. 975; Broderick Dep. at 16-18, App. 15-17; Caples Decl. ¶ 4, App. 979; Choo Decl. ¶ 4, App. 981; Chung Decl. ¶ 4, App. 983; Clarke Decl. ¶ 4, App. 985; English Decl. ¶ 4, App. 987; Forman Decl. ¶ 4, App. 989; Fry Dep. at 106-07, App. 92-93; Glassman Decl. ¶ 4, App. 991; Hattemer Dep. at 8-9, App. 117-18; Henthorn Dep. at 23, 34-35, App. 144, 149-50; Hunter Decl. ¶ 4, App. 993; Ivey Decl. ¶ 4, App. 995; Jenike Dep. at 11-12, App. 157-58; Kereiakes Decl. ¶ 4, App. 999; Mitts Decl. ¶ 4, App. 1015; Murtaugh Decl. ¶ 4, App. 1001; Pelberg Decl. ¶ 4, App. 1003; Schneider Decl. ¶ 4, App. 1005; Smith Decl. ¶ 4, App.

repeatedly indicated that the cardiologists needed to refer patients to obtain it. But they did not. For instance, when Fry asked about the process in 1996, Von Zychlin indicated only that the hospital assigned time based on the physician's activity "to assure a physician has practiced at the institution a sufficient amount of time to evaluate their expertise so a minimum standard of care is maintained." (Dep. Ex. 3 at 1, App. 336.) Similarly, it is undisputed that Seim and Wietholter told Dr. Fry and other cardiologists that they did not know how panel was assigned when asked in October 1999. (Fry. Dep. at 106-09, App. 92-95; Seim Dep. at 143, App. 214.) No administrator, moreover, ever told any cardiologist, including Dr. Fry, that the hospital offered panel as an inducement to refer patients.[7] That they did not do so corroborates that their intent was simply to maintain quality care. In turn, that many Ohio Heart cardiologists did not know how panel was assigned confirms that they lacked any intent to refer patients in return for it.

Third, the evidence shows that panel would have been distributed in roughly the same proportion no matter how it was allocated. When, for example, a new method was developed for 2005, the allocations were "very similar to what had been provided under MDA and even prior

(continued…)

1015, Stewart-Dehner Decl. ¶ 4, App. 1007; Thoresen Decl. ¶ 4, App. 1009; Toltzis Dep. at 129, App. 278; Whang Dep. at 20-21, App. 307; Waller Decl. ¶ 4, App. 1013; Wietmarschen Dep. at 29-30, 65-66, App. 324-25, 328-29.)

[7] (*See* Behrens Decl. ¶¶ 3-5, App. 975; Broderick Dep. at 16-18, App. 15-17; Caples Decl. ¶¶ 3-5, App. 979; Choo Decl. ¶¶ 3-5, App. 981; Chung Decl. ¶¶ 3-5, App. 983; Clarke Decl. ¶¶ 3-5, App. 985; Desai Dep. at 28, 46-47, App. 77, 79; English Decl. ¶¶ 3-5, App. 987; Forman Decl. ¶¶ 3-5, App. 989; Fry Dep. at 106-08, App. 92-94; Glassman Decl. ¶¶ 3-5, App. 991; Hattemer Dep. at 50-51, App. 128-29; Henthorn Dep. at 26, 37-39, App. 146, 151-53; Hunter Decl. ¶¶ 3-5, App. 993; Ivey Decl. ¶ 4, App. 995; Jenike Dep. at 18, App. 160; Kereiakes Decl. ¶¶ 3-5, App. 999; Murtaugh Decl. ¶¶ 3-5, App. 1001; Pelberg Decl. ¶¶ 3-5, App. 1003; Schneider Decl. ¶¶ 3-5, App. 1005; Thoresen Decl. ¶¶ 3-5, App. 1009; Snavely Dep. at 9, App. 229; Stewart-Dehner Decl. ¶¶ 3-5, App. 1007; Suresh Dep. at 74-75, App. 239; Toltzis Dep. at 128-29, App. 277-78; Whang Dep. at 20-21, App. 307; Waller Decl. ¶¶ 3-5, App. 1013; Wietmarschen Dep. at 31-32, 55-56, App. 325, 327.)

to MDA as far as the amount of coverage." (Croushore Dep. at 163, App. 71; *see* Dep. Ex. 147, App. 414.) When any qualified cardiologist could obtain time, in other words, cardiologists who had never received it were not "breaking down the doors wanting to do panel." (Hattemer Dep. at 31, App. 122.) Rather, those doctors regularly at the hospital who had historically staffed panel kept their same amount with little if any change. (Toltzis Dep. at 168-69, App. 279-80.)

Ohio Heart cardiologists in particular would not have been induced because they were the biggest group and would take a large percentage of panel *no matter how it was allocated*. As a competing group leader put it, "[e]very hospital in the city in this region, probably in the United States, that you look at, you're going to have a dominant cardiology group. They're going to do most of the panels." (Wietmarschen Dep. at 88-89, App. 331.) And "[i]t was general knowledge there that Ohio Heart had . . . most of the cardiologists on staff at Christ Hospital and, therefore, they did most of the panel," just as his group "had much more panel at another hospital than Ohio Heart because Ohio Heart wasn't there." (*Id.* at 34-35, App. 326.)

Any possible inducement, in other words, would only be the marginal increase in time Ohio Heart would receive under a volume-based method above the amount they would receive under alternative methods. And yet even under the volume-based method, Ohio Heart often did not take as much panel as other cardiologists thought it should. To that end, when MDA began to take over the panel-allocation responsibility in 2000, non-Ohio Heart cardiologists, including Dr. Fry, estimated among themselves that Ohio Heart should take seventy percent in 2001. (Fry Dep. at 118-20, App. 97-99; Dep. Ex. 56, App. 388.) Yet when MDA considered the previous year's volume statistics, Ohio Heart received only sixty percent. (Dep. Ex. 66 at 2-3, App. 401-02.) And the first year that the hospital established the new method, Ohio Heart refused to take roughly twenty percent of what it was offered. (Broderick Dep. at 284, App. 44; Dep. Ex. 147,

App. 414.) Because Ohio Heart cardiologists would receive substantial time under any possible method, administrators would not have viewed panel as a way to get Ohio Heart to send more patients there. Nor would Ohio Heart cardiologists have viewed it as an inducement to do so.

Fourth, panel time's value depended on each cardiologist, as the opportunity to do panel work was not generally valuable across all cardiologists at the hospital. To be sure, Dr. Fry and other physicians indicated that they found the opportunity lucrative because they could receive fair-market pay from patients for the panel work. (*See* Fry Dep. at 38, App. 84; Desai Dep. at 11, App. 76; Toltzis Dep. at 171, App. 281.) But, given the significant opportunity costs involved, many others placed little or no value on panel work.[8] These physicians indicated, among other things, that "it wasn't worth their time" to staff panel (Wietmarschen Dep. at 31, App. 325) or that panel presented an "extreme hardship" (Dep. Ex. 292 at 2, App. 585). Many took panel only "to support the hospital" (Jenike Dep. at 80, App. 163), viewing it as a "service" (Snavely Dep. at 14, App. 230). And interventional cardiologists specialized in areas other than diagnostic testing, such as performing angioplasties, and preferred working in those areas instead. (Whang Dep. at 19, App. 307; Croushore Dep. at 64, App. 63.)

Likewise, administrators did not believe that all cardiologists valued panel time. To the contrary, their experience confirmed that the value of panel depended on each cardiologist. Administrators felt that many saw panel as a responsibility rather than a benefit. (Croushore Dep. at 64, App. 63.) For example, while a few cardiologists "coveted" the GXT panel in the mid 1990s (Dep. Ex. 2 at 1, App. 334; Croushore Dep. at 19-20, App. 58-59), by 1999 administrators were having trouble covering even that panel (Wall Dep. at 44, App. 293). They routinely

[8] (*See* Hattemer Dep. at 32, 70-71, App. 123, 131-32; Henthorn Dep. at 31, 33-34, App. 147-49; Jenike Dep. at 20, 82-83, App. 161, 164-65; Snavely Dep. at 14, App. 230; Suresh Dep. at 74, App. 239; Whang Dep. at 19-20, App. 307; Wietmarschen Dep. at 31, App. 325.)

experienced difficulties in obtaining timely coverage.[9] Measured against this backdrop, it becomes clear that administrators would not use panel as a device to induce referrals. Had they truly been willing to engage in a far-reaching criminal conspiracy, involving hundreds of practicing cardiologists in Cincinnati, they would have offered something of universal value, not something for which the value depended on the cardiologist's particular practice.

Fifth, numerous physicians, both from Ohio Heart and from competing groups, did not consider panel to be an inducement and did not refer even a single patient to the hospital to obtain panel time:

> Dr. Thomas Broderick: "[He] would never have sent anybody to Christ to get panel time. That's just not – not the way that you practice." (Broderick Dep. at 272, App. 40.)
>
> Dr. Harry Fry: He "certainly" "never admitted patients or referred patients or utilized The Christ Hospital in any way to get panel time." (Fry Dep. at 108, App. 94.)
>
> Dr. Charles Hattemer: He never "refer[red] a patient to The Christ Hospital to get panel time" for himself or "for others in [his] group." (Hattemer Dep. at 50-51, App. 128-29.)
>
> Dr. Richard Henthorn: He never "treat[ed] patients at The Christ Hospital for the express purpose of obtaining heart station panel time there." (Henthorn Dep. at 39, App. 153.)
>
> Dr. Thomas Ivey: "As a cardiac surgeon, [he] did not serve on any Heart Station panel at The Christ Hospital." "The manner in which time on any Heart Station panel at The Christ Hospital was assigned to cardiologists between 1997 and 2004 played no part in [his] decision to perform cardiac surgeries at or otherwise refer patients to The Christ Hospital." (Ivey Decl. ¶¶ 5-6, App. 995.)
>
> Dr. F. Thomas Jenike: He never "direct[ed] any patients from Deaconess to The Christ Hospital in order to get panel time" and never "direct[ed] any patient from Mercy Fairfield to The Christ Hospital to get panel time." (Jenike Dep. at 18, App. 160.)
>
> Dr. Daniel Snavely: He did not view the use of volume statistics as an "inducement to send business to the hospital," but merely as "a math problem that equitably divided time." (Snavely Dep. at 96, App. 234.)

[9] (*See* Hayes Dep. at 40, App. 136; S. McDonald Dep. at 55-56, App. 187-88; Morneault Dep. at 94, App. 193; Seim Dep. at 125-26, App. 211; Wall Dep. at 32-33, 44, App. 290, 293.)

> Dr. D.P. Suresh: He never "referred a patient to Christ Hospital to get panel time." (Suresh Dep. at 37, App. 237.)
>
> Dr. Robert Toltzis: He "was only working at The Christ Hospital" and "that had nothing to do with panel time." (Toltzis Dep. at 129, App. 278.)
>
> Dr. David Whang: His "ability to get time in the heart station" was never "a factor in [his] determining where to treat patients." (Whang Dep. at 18, App. 307.)
>
> George Wietmarschen: No physician from Comprehensive Cardiology Consultants was ever "rewarded panel time for referring patients to The Christ Hospital." (Wietmarschen Dep. at 71, App. 330.)[10]

Confirming the point, no cardiologist provided unnecessary or inappropriate medical services, something one would expect if cardiologists truly were attempting to solicit panel by inflating their referral numbers.[11] In short, that cardiologists did not consider panel an inducement to refer patients—as evidenced by the fact that no unnecessary services were performed—supports the conclusion that administrators would likewise not use it as one.

Sixth, agents for The Christ Hospital or The Health Alliance lacked any motive to offer kickbacks. For one thing, the hospital had the "best" reputation "in the region" for cardiac services, (Seim Dep. at 154, App. 215), and was ranked as Cincinnati's Most Preferred Hospital year after year (TCH Fiscal Accomplishments 2004, at 2, App. 968). Many cardiologists attested

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[10] (*See also* Behrens Decl. ¶ 5, App. 975; Caples Decl. ¶ 5, App. 979; Choo Decl. ¶ 5, App. 981; Chung Decl. ¶ 5, App. 983; Clarke Decl. ¶ 5, App. 985; English Decl. ¶ 5, App. 987; Forman Decl. ¶ 5, App. 989; Glassman Decl. ¶ 5, App. 991; Hunter Decl. ¶ 5, App. 993; Kereiakes Decl. ¶ 5, App. 999; Murtaugh Decl. ¶ 5, App. 1001; Pelberg Decl. ¶ 5, App. 1003; Schneider Decl. ¶ 5, App. 1005; Stewart-Dehner Decl. ¶ 5, App. 1007; Thoresen Decl. ¶ 5, App. 1009; Toltzis Dep. at 129, App. 278; Waller Decl. ¶ 5, App. 1013.)

[11] (*See* Behrens Decl. ¶ 2, App. 975; Broderick Dep. at 291, App. 47; Caples Decl. ¶ 2, App. 979; Choo Decl. ¶ 2, App. 981; Chung Decl. ¶ 2, App. 983; Clarke Decl. ¶ 2, App. 985; English Decl. ¶ 2, App. 987; Forman Decl. ¶ 2, App. 989; Fry Dep. at 23-24, App. 82-83; Glassman Decl. ¶ 2, App. 991; Henthorn Dep. at 45, App. 154; Hunter Decl. ¶ 2, App. 993; Ivey Decl. ¶ 6, App. 995; Jenike Dep. at 84, App. 166; Kereiakes Decl. ¶ 2, App. 999; Murtaugh Decl. ¶ 2, App. 1001; Pelberg Decl. ¶ 2, App. 1003; Schneider Decl. ¶ 2, App. 1005; Snavely Dep. at 29-30, App. 232-33; Stewart-Dehner Decl. ¶ 2, App. 1007; Suresh Dep. at 75, App. 239; Thoresen Decl. ¶ 2, App. 1009; Toltzis Dep. at 209, App. 282; Waller Decl. ¶ 2, App. 1013.)

to its high-quality reputation.[12] Due to this demand, administrators had trouble accommodating "the volumes that [they] were getting" for cardiac services. (Seim Dep. at 155, App. 215.) The hospital thus had no incentive to engage in a scheme that risked its very existence.

For another, even if the hospital had been desperate for business, the employees themselves had no *personal* motive to participate in a scheme that could land them in prison. (*Id.* at 136-37, App. 212-213.) This lack of personal motive in an Anti-Kickback Statute case dooms the United States' legal theory. *See Klaczak*, 458 F. Supp. 2d at 677. Indeed, under such circumstances, it is incredible to think "that the Hospital Defendants' agents knowingly and willfully were prepared to violate federal criminal law (and face all of the personal sanctions that might entail)" "for no personal gain." *Id.* The same is true here. The absence of personal motive shows that administrators acted only for the legitimate reasons they have expressed.

At bottom, the United States wants this Court to find a jury question on defendants' intent because the panel-allocation method relied upon volume metrics. But "[i]t's part of standard business practice at every hospital in the country" to look at these statistics. (Croushore Dep. at 26, App. 61; *see* Ronning Expert Report at 31, App. 907.) Many hospitals nationwide, for example, routinely provide physicians with a block of time in operating rooms based upon some measure of their volumes. (Seim Dep. at 166, App. 217; Von Zychlin Decl. ¶ 4, App. 1011.) Similarly, volume statistics often are used as quality measures (Broderick Dep. at 253, App. 37), and hospitals condition privileges on a admissions to assess clinical proficiency. (*See* Univ. Hosps. Health Sys. Public Comments at 7, App. 669.) To permit this case to proceed to trial simply because volume metrics were utilized would, it must be said, open up to challenge many standard, national practices based on nothing more than sheer speculation that hospitals acted

[12] (*See* Broderick Dep. at 290, App. 46; Hattemer Dep. at 51, App. 129; Henthorn Dep. at 25, App. 145; Jenike Dep. at 83, App. 165; Snavely Dep. at 8-9, App. 229.)

with a corrupt intent. Simply put, because the United States lacks sufficient evidence to prove that defendants harbored the intent necessary under the Anti-Kickback Statute, summary judgment is warranted on all counts.

II. SUMMARY JUDGMENT IS PROPER BECAUSE THE UNITED STATES HAS NOT SHOWN THAT THE ALLEGED VIOLATION OF THE ANTI-KICKBACK STATUTE CAN CREATE LIABILITY UNDER THE FALSE CLAIMS ACT.

Defendants are entitled to summary judgment for the additional reason that, even assuming the United States has proved a violation of the Anti-Kickback Statute, it has failed to prove a violation of the False Claims Act. To do so, the United States must satisfy several additional elements. To begin with, it must show that the alleged violation created a "false or fraudulent claim." 31 U.S.C. § 3729(a)(1)-(3); *see Conner*, 543 F.3d at 1211. It must also prove that defendants submitted a claim "knowing[]" about the alleged violation. 31 U.S.C. § 3729(a); *see Lamers*, 168 F.3d at 1020. Finally, the United States must illustrate that the alleged violation was "material" to its payment decision. *See United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 444 (6th Cir. 2005). The United States has not established sufficient evidence on these elements, which proves fatal to all its counts.

A. The United States Lacks Evidence That Any Claims Were False.

The United States must present evidence to prove that defendants' alleged violation of the Anti-Kickback Statute generated "false or fraudulent claims." It has not done so for two reasons. The evidence shows that any certifications of compliance with the Anti-Kickback Statute were, one, not objectively false, and, two, not a condition of government payment.

1. Any certifications of compliance with the Anti-Kickback Statute were not "objectively false."

The United States' False Claims Act theory fails because it has not presented sufficient evidence that defendants made "objectively false" statements. Under the "falsity" element, "the

statement or conduct alleged must represent an objective falsehood." *Wilson*, 525 F.3d at 376; *see United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. App'x 980, 982 (10th Cir. 2005) ("At a minimum the FCA requires proof of an objective falsehood."). An example of this kind of falsehood "is the representation that a resident worked five days a week at a hospital when he worked only three." *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 832 (W.D. Mich. 2000), *aff'd*, 24 Fed. App'x 491 (6th Cir. Dec 12, 2001) (internal quotation marks omitted). In contrast, "imprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false." *Lamers*, 168 F.3d at 1018. Nor are "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ." *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) (Spiegel, J.).

Here, defendants provided medically necessary and appropriately billed services.[13] Thus, the United States has no evidence that they submitted "factually false" claims, *i.e.*, those with "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Conner*, 543 F.3d at 1217 (internal quotation marks omitted). "Instead, this case involves disputed legal interpretations" over the Anti-Kickback Statute, placing it outside the conduct sought to be reached by the False Claims Act. *Little v. ENI Petroleum, Inc.*, No. CIV-06-120-M, 2009 WL 2424215, at *4 (W.D. Okla. July 31, 2009).

[13] (*See* Behrens Decl. ¶ 2, App. 975; Broderick Dep. at 291, App. 47; Caples Decl. ¶ 2, App. 979; Chung Decl. ¶ 2, App. 983; English Decl. ¶ 2, App. 987; Forman Decl. ¶ 2, App. 989; Fry Dep. at 23-24, App. 82-83; Glassman Decl. ¶ 2, App. 991; Henthorn Dep. at 45, App. 154; Hunter Decl. ¶ 2, App. 993; Ivey Decl. ¶ 6, App. 995; Jenike Dep. at 84, App. 166; Kereiakes Decl. ¶ 2, App. 999; Murtaugh Decl. ¶ 2, App. 1001; Pelberg Decl. ¶ 2, App. 1003; Schneider Decl. ¶ 2, App. 1005; Snavely Dep. at 29-30, App. 232-33; Suresh Dep. at 75, App. 239; Thoresen Decl. ¶ 2, App. 1009; Toltzis Dep. at 209, App. 209; Waller Decl. ¶ 2, App. 1013.)

While the Court rejected defendants' motion-to-dismiss argument concerning the Anti-Kickback Statute's scope (R.95 at 11-18), the evidence produced in discovery provides three additional reasons why "reasonable minds" could have differed over whether the use of volume statistics in granting panel time implicated the Anti-Kickback Statute. *Roby*, 100 F. Supp. 2d at 625. *First*, the United States has admitted that, during the relevant period, it did not "publish[] guidance specifically addressing the exact factual circumstances" at issue here, namely, allocating panel based upon a physician's use of the hospital. (United States' Admissions at 20, 35, App. 722, 737.) The United States likewise admitted that it did not publish specific guidance on similar topics, such as whether a hospital can consider volumes in allocating time in operating rooms, creating emergency-call lists, or awarding medical-staff privileges. (*Id.*) And it admitted that it had "never brought a criminal action or a civil case alleging a violation of the False Claims Act" based upon these facts. (*Id.* at 33, App. 735.)

Case law proves that this lack of specific guidance eliminates any objective falsehood. In a similar case, the plaintiff alleged that the defendant submitted false claims "when viewed in light of the general regulations governing reimbursement for physician services." *Swafford*, 98 F. Supp. 2d at 828. The court held that these regulations did not establish an objective falsehood because of "the lack of specific billing regulations" on the conduct at issue. *Id.* at 828. Given the United States' admitted lack of specific guidance, the same logic applies here. *Cf.* S. Rep. No. 109, 100th Cong., 1st Sess. 27, *reprinted in* 1987 U.S.C.C.A.N. 682, 707-08 (recognizing that Anti-Kickback Statute's general terms "created uncertainty among health care providers as to which commercial arrangements are legitimate and which are proscribed").

Second, that absence of specific guidance is all the more egregious here because the United States had been notified of the need for clarification. The record shows that many groups

publicly interpreted the Anti-Kickback Statute the same way defendants did, further confirming that "reasonable minds may differ" on this legal debate. *Roby*, 100 F. Supp. 2d 619. In 2002, the American Medical Association told the United States that hospitals had been requiring physicians to refer a certain number of patients to obtain staff privileges, calling these requirements "pay to play arrangements." (06/12/02 Am. Med. Ass'n Letter to OIG, attaching 12/02/99 Letter at 10, App. 694.) The United States did not crackdown on these so-called pay-to-play schemes. Instead, because the legal landscape was too murky, it asked for public comment on the issue, "Are hospital staff privileges 'remuneration'?" OIG, *Solicitation of New Safe Harbors and Special Fraud Alerts*, 67 Fed. Reg. 72894, 72895 (Dec. 9, 2002).

In response, many hospitals interpreted the Anti-Kickback Statute's remuneration requirement to exclude privileges, relying on the same interpretation as defendants.[14] They indicated that when a hospital grants privileges it does not make an "in cash" or "in kind" payment (AHA Public Comments at 2, App. 593), just as the granting of panel time is not an "in cash" or "in kind" payment. They also pointed out that any monetary benefit from privileges, like any monetary benefit from panel, arises only from the third-party "payment made by the physician's patient or his/her insurer for professional services rendered." (*Id.*) And privileges "permit the physician to use the facilities, equipment and personnel of the hospital without cost" (Horty, Springer & Mattern Public Comments at 6, App. 616), just as panel permits the physicians to use equipment and staff. But these "benefit[s] to physicians [are merely] incidental to the purpose of the Hospital to serve its patients." (*Id.*)

[14] (*See, e.g.*, Am. Hosp. Ass'n (AHA) Public Comments, App. 592; Ohio Hosp. Ass'n Public Comments, App. 660; Mercy Health Partners Public Comments, App. 636; Univ. Hosps. Health Sys. Public Comments, App. 663; OhioHealth Corp. Public Comments, App. 654.)

Like defendants, moreover, hospitals noted that a finding that privileges were remuneration would "open[] the door to any 'business opportunity' being remuneration," making it "impossible to determine what conduct violates the" Anti-Kickback Statute and Stark Law. (Mo. Hosp. Ass'n Public Comments at 2, App. 640.) Under the Stark Law, for example, physicians cannot refer to hospitals with which they have a "financial relationship." 42 U.S.C. § 1395nn(a)(1). The law defines "financial relationship" as any "compensation arrangement," which, in turn, is defined as "any remuneration" "in cash or in kind." *Id.* § 1395nn(a)(2)(B), (h)(1)(A)-(B). As a result, if privileges are remuneration, they would create a prohibited financial relationship, "leading to the anomalous result that medical staff members could not refer to any hospital that granted them privileges." (Az. Hosp. & Healthcare Ass'n Public Comments at 5, App. 597.) So too, if the opportunity to serve on panel is remuneration, the opportunity to take panel would legally bar physicians from being able to do so. These public comments illustrate that the United States cannot meet the objective-falsehood requirement.

While other groups suggested that privileges should be treated as remuneration, their arguments only reaffirm the lack of an objective falsehood in this case. They illustrate that the United States can no longer downplay the legal dispute over privileges by arguing that privileges are less valuable than panel. (*See* R.83 at 13-14.) Unlike for panel, physicians universally indicated that "hospital privileges are[,] without a doubt, an item of economic value in all cases." (Am. Acad. of Otolaryngology Public Comments at 1, App. 590.) They asserted that privileges were "crucial to enabling a physician to earn an income" (*id.* at 4, App. 593); "offer[ed] the opportunity to earn fees on services to inpatients" (Am. Acad. of Neurology at 1, App. 588); gave physicians "access to the patients covered by a major insurance carrier" (N. Ohio Med. Ass'n Public Comments at 3, App. 649); and often provided "the referral source for the patients

themselves" (Cal. Med. Assoc. Public Comments at 9, App. 605). Physicians thus saw privileges as necessary to their "very livelihood." (Mo. State Med. Ass'n Public Comments, App. 648).

As a result, the legal dispute over whether hospitals can allocate privileges based on referrals directly carries over to whether hospitals can allocate panel based on referrals. Indeed, in 2003, administrators in this case analogized to these "economic credentialing issues" when contemplating whether they could assign panel solely to reliable physicians. (Croushore Dep. at 146-47, App. 67-68.) Because it was reasonable to believe that the United States had "never viewed the granting of hospital staff privileges to physicians as 'remuneration' under the anti-kickback law" (AHA Public Comments at 1, App. 592), it was necessarily reasonable to believe that the United States had never viewed the granting of panel time as remuneration either. To find an objective falsehood, then, the Court here must conclude not simply that *defendants* unreasonably interpreted the Anti-Kickback Statute but also that the *entire hospital community* did.

Third, the evidence now illustrates that many hospitals relied on volume criteria for panels, either directly or indirectly. Some local hospitals based panel "on the physicians who actually practiced at the hospital." (Wietmarschen Dep. at 18, App. 323.) One assigned panel privileges "related to the number of consultations that were performed by the physicians during the previous calendar year." (Abbottsmith Dep. in *UIMA v. MDA* at 15, App. 11.) Another allocated panel, in part, based upon the "volume of patient care administered by the physician at the hospital." (Desai Dep. at 38-39, App. 78-79.) Prior to this lawsuit, this may have been a national practice. In the public comments on privileges, one physician indicated that a New York hospital had revoked his "privileges to read Electrocardiograms, Echocardiograms, and Stress Tests" in part because of his "limited hospital admissions." (02/04/03 Iqbal Public

Comments, App. 635.) And the hospital's panel research indicated that a cardiology group received seventy-five percent of panel at a California hospital because "it had strong leverage with the hospital." (Dep. Ex. 9 at 2, App. 374.) That many hospitals used volumes in some manner supports the conclusion that defendants did not submit false claims by doing so here.

All this new evidence, when considered with defendants' arguments on the motion to dismiss, suggests that the Court may want to reconsider its prior order that held panel time could constitute remuneration under the Anti-Kickback Statute. (R.95 at 15-17.) The evidence shows that the Court's decision may have far-reaching consequences and suggests that many hospitals could be in regulatory non-compliance. At the very least, the evidence confirms that reasonable minds could differ on the issue. Given the lack of clarity, plainly the United States has not established "an objective falsehood." *Wilson*, 525 F.3d at 376.

2. Defendants did not certify compliance with the Anti-Kickback Statute as a condition of payment.

To turn a violation of the Anti-Kickback Statute into a false claim, the United States must also present evidence that defendants certified that the specific claim at issue complied with the Anti-Kickback Statute; that compliance was "*a condition* to government payment" of that claim; and that defendants failed to comply. *Conner*, 543 F.3d at 1217 (internal quotation marks omitted); *see Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001). This type of "legally false" claim "can rest [on] one of two theories—express false certification, and implied false certification." *Conner*, 543 F.3d at 1217. Under the implied-certification theory, the United States must show that the mere "act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Mikes*, 274 F.3d at 699. To narrow this theory's vague reach, courts have permitted it "only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in

order to be paid." *Id.* at 700 (emphasis added); *see United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 414-15 (6th Cir. 2002) (citing *Mikes* with approval and relying on implied-certification theory when regulation expressly linked payment to compliance).

Under the express-certification theory, by comparison, a defendant expressly "certifies compliance with a statute or regulation *as a condition to governmental payment*." *Mikes*, 274 F.3d at 697 (emphasis added). The applicable certification underlying a claim, in other words, must *expressly* "state that compliance is a prerequisite to payment." *Conner*, 543 F.3d at 1218. In contrast, "[a] general statement of adherence to all regulations or statutes governing participation in a program through which federal funds are received is insufficient as a basis of False Claims Act liability." *Graves*, 284 F. Supp. 2d at 501. Here, neither theory is available to the United States.

a. The United States cannot rely on an implied-certification theory.

The United States cannot resort to the implied-certification doctrine because the Anti-Kickback Statute does not "expressly state[]" that health care providers "must comply in order to be paid" under health care programs. *Mikes*, 274 F.3d at 700; *see United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009) (rejecting implied-certification theory for Anti-Kickback Statute because it did not "expressly state[] that the provider must comply in order to be paid"); *Urbanek*, 2003 U.S. Dist. LEXIS 27469, at *23 ("FCA liability cannot be based on 'implied certifications' of compliance with the Anti-Kickback Statute, because the Anti-Kickback Statute itself does not expressly state that a provider must comply with the statute in order to be paid."). Instead, the statute imposes imprisonment and/or fines for non-compliance. *See* 42 U.S.C. § 1320a–7b(b).

A comparison of the Anti-Kickback Statute with the Stark Law reinforces the conclusion that the former does not permit implied certification. Unlike the Anti-Kickback Statute, the

Stark Law expressly indicates that "[n]o payment may be made under this subchapter for a designated health service which is provided in violation of [its provisions]." *Id.* § 1395nn(g)(1). Courts "presume that, where words differ as they differ here, Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Burlington N. & Santa Fe Ry. Co. v. White*, 548 U.S. 53, 63 (2006) (internal quotation marks omitted). As reflected by the Stark Law, Congress knows how to expressly make compliance a condition of health care payment. And, notably, it did not do so with the Anti-Kickback Statute. Because the United States alleges no Stark Law violation, it cannot use the implied-certification theory here.

b. The United States cannot show that defendants expressly certified compliance with the Anti-Kickback Statute.

The United States' express-certification theory fares no better. The United States relies on statements that do not certify compliance with the Anti-Kickback Statute or that broadly certify compliance with all regulations. To begin with, it cites certifications in CMS-1500 forms as evidence that Ohio Heart and third-party cardiologists expressly certified that the claims they submitted were in compliance with the Anti-Kickback Statute. (R.53 at 12; *see, e.g.*, CMS 1500 Form at 2, App. 757.) But none indicates, as it must, that the particular claim at issue complied with the Anti-Kickback Statute. (*See id.*) Instead, the forms certify only that the claim was for necessary services. (*Id.*) *Cf. Mikes*, 274 F.3d at 698. The forms provide no basis for an express-certification theory.

Similarly, to prove that The Christ Hospital and The Health Alliance expressly certified that their claims complied with the Anti-Kickback Statute, the United States points to the cost reports submitted between 1997 and 2004. (*See* R.53 at 23-24; 1997 to 2004 Cost Report Certifications, App. 673-680.) Each report initially indicated that the payment of kickbacks or other illegal conduct may result in fines, imprisonment, or administrative action:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report where [sic] provided or produced through the payment direct or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

(*Id.*) The administrator who signed each report, The Health Alliance's Vice President of Finance, then certified that the services listed in the report were provided in compliance with all health care laws and regulations:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [The Christ Hospital] for the [relevant] cost reporting period . . . , and that to the best of my knowledge and belief, it is a true, correct, and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of the health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(*Id.*)

This language does not suffice for the express-certification theory. For starters, while the reports certified compliance with all health care laws and regulations, they nowhere "state[d] that compliance" with the Anti-Kickback Statute was "a prerequisite to payment" under health care programs. *Conner*, 543 F.3d at 1218. Because the cost reports failed to *expressly* condition payment on compliance, they do not satisfy express-certification requirements. *Id.*; *see United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972, 978-79 (W.D. Tenn. 2007) (granting summary judgment because cost-report certification did not condition payment on compliance).

Furthermore, because the cost reports acknowledge compliance with everything under the sun, they represent the same far-reaching certifications courts have squarely rejected as a basis for False Claims Act liability. *See United States ex rel. Lacy v. New Horizons, Inc.*, No. 08-

6248, 2009 WL 3241299, at *6 (10th Cir. Oct. 9, 2009) (rejecting use of "annual cost reports" for False Claims Act liability); *Graves*, 284 F. Supp. 2d at 501 (rejecting "general statement of adherence to all regulations or statutes governing participation in a program . . . as basis for False Claims Act liability"); *United States ex rel. Lobel v. Express Scripts, Inc.*, No. 05-cv-02707-JF, 2008 WL 5083115, at *2 (E.D. Pa. Dec. 1, 2008) (dismissing case because "general certification" did not suffice).

In addition, the reports merely suggested that a regulatory violation *may* lead to punishment. Courts have found that payment was not conditioned on compliance where the relevant provisions, like those here, merely suggested that discretionary fines or administrative action might ensue for non-compliance. *See United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 389-90 (5th Cir. 2008) (finding that contract did not "den[y] benefits to the Defendants in the event of a false certification" when it merely provided a range of remedies); *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) (noting that statute did not condition payment on compliance because it merely authorized administrative action or fines for non-compliance).

As a final matter, the United States has now admitted that, during the relevant period, "it was not and has not been the policy of the Centers for Medicare & Medicaid Services (CMS) to instruct [its contractors] to withhold payment of Medicare claims submitted by providers . . . based on alleged or suspected violations of the Anti-Kickback Statute." (United States' Admissions at 39, App. 741.) Likewise, Medicare regulations do not specifically indicate that compliance with the Anti-Kickback Statute is a condition of payment. *See generally* 42 C.F.R. Part 424. These facts show that, while compliance may have been a condition of *participation* in Medicare, it was not a condition of *payment*. *See also* 42 U.S.C. § 1320a-7a (permitting United

States to exclude providers from health care program for Anti-Kickback Statute convictions). That proves fatal to the United States' case. Numerous courts have refused to treat "conditions of participation" in a government program (the violation of which could lead to punishment) as "conditions of payment" for purposes of the False Claims Act. *See Conner*, 543 F.3d at 1220 (noting that "courts are careful to distinguish between conditions of program *participation* and conditions of *payment*"); *Mikes*, 274 F.3d at 701-02; *Kennedy*, 610 F. Supp. 2d at 947; *Landers*, 525 F. Supp. 2d at 978-79. This Court should do the same.

c. The case law cited at the motion-to-dismiss stage no longer controls.

Some courts have permitted False Claims Act plaintiffs to proceed on the theory that the United States conditioned health care payments on compliance with the Anti-Kickback Statute. But these courts did not establish the bright-line rule that Medicare or Medicaid disbursements always required compliance with the Anti-Kickback Statute. To the contrary, most of this law was decided at the motion-to-dismiss stage. Like this Court, (*see* R.95 at 5-6), the courts had to accept as true the allegations that compliance with the Anti-Kickback Statute was a condition of payment.[15] *See, e.g., United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259-60 (11th Cir. 2005). In *McNutt*, for example, "[n]either party dispute[d] that compliance with federal health care laws, including the [Anti-Kickback Statute], [was] a condition of payment." 423 F.3d at 1259. The court thus denied a motion to dismiss because it accepted as true the allegation that Anti-Kickback Statute compliance was necessary for payment. *Id.* at 1260.

[15] *See also United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Thomas v. Bailey*, No. 4:06-cv-00465, 2008 WL 4853630, at *8 (E.D. Ark. Nov. 6, 2008); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32-33 (D.D.C. 2003).

The opinions outside this preliminary stage harmlessly conflated the Anti-Kickback Statute and Stark Law as both were at issue, unlike here. In *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), for example, the court noted that "compliance with the Stark and Anti-Kickback Statutes is a *statutory* condition of payment." *Id.* at 724 (emphasis added). That conclusion is simply wrong as applied to the Anti-Kickback Statute. *See Kennedy*, 610 F. Supp. 2d at 946. And the Seventh Circuit's opinion affirming relied solely on the Stark violation. *See United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008). That Stark violation compelled the United States to refuse payment because it had no "authority to waive [enforcement of its sanctions] for 'minor' and 'technical' violations." *Solinger*, 543 F. Supp. 2d at 686 (internal quotation marks omitted).

Just the opposite is true for the Anti-Kickback Statute. The United States has repeatedly excused violations. In "advisory opinions," it has told health care entities that the arrangement at issue "would potentially generate prohibited remuneration under the anti-kickback statute," but that it would "not subject [the Requestor] to sanctions for violations of the anti-kickback statute." OIG Advisory Opinion No. 00-4 (June 27, 2000), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_4.htm; *see* 73 Fed. Reg. 23528, 23693 (Apr. 30, 2008) (noting that the "OIG has issued advisory opinions in which it concluded that the proposed arrangement presents a low risk of abuse and, therefore, it would exercise its prosecutorial discretion not to impose sanctions."). If the law compelled compliance for payment, federal agencies could not waive violations. These opinions confirm that no law required participants to comply with the Anti-Kickback Statute to be paid under health care programs. And because compliance with the Anti-Kickback Statute was not a condition of payment, summary judgment is appropriate.

B. The United States Has Failed To Present Sufficient Evidence That Defendants Knowingly Violated The Anti-Kickback Statute.

The United States has also failed to present sufficient evidence to show that defendants "knowingly" submitted false claims or "knowingly" made false statements. 31 U.S.C. § 3729(a). Where, as here, "legally false" claims are at issue, the United States must show that a defendant submitted a claim with "actual knowledge" that the claim violated the relevant regulation or that the defendant acted in "deliberate ignorance" or "in reckless disregard" as to whether the claim did so. *Id.* § 3729(b). In other words, "simple negligence" or "honest mistakes" about legal compliance do not fall within the False Claims Act's domain. *See United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 949 (10th Cir. 2008); *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765 (8th Cir. 2002). Rather, the alleged legal "violations . . . are not fraud unless the violator knowingly lies to the government about them." *Lamers*, 168 F.3d at 1020.

This intent element has objective and subjective components. Initially—as expressed in *Safeco Insurance Company of America v. Burr*, 551 U.S. 47 (2007), for the Fair Credit Reporting Act—a court must determine whether the defendant's conduct complied with a reasonable interpretation of the underlying regulation. If it did so, the defendant cannot be liable "whatever [its] subjective intent may have been." *Safeco*, 551 U.S. at 70 n.20; *see United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, No. 4:07-cv-0465-JAJ, 2009 WL 3003258, at *14-15 (S.D. Iowa Sept. 21, 2009) (incorporating *Safeco* into False Claims Act); *United States ex rel. Pritsker v. Sodexho*, No. 03-6003, 2009 WL 579380, at *17 (E.D. Pa. 2009) (same); John T. Boese, Civil False Claims and Qui Tam Actions § 2.06[C] (3d ed. 2009) (same). Only if no reasonable interpretation existed need the court consider subjective intent.

Here, the evidence proves that defendants' conduct complied with a reasonable interpretation of the Anti-Kickback Statute for the same reasons that no objective falsehood

exists. *See supra* at Section II.A.1. But even if the Court considers subjective intent, it only confirms that the Court should grant summary judgment to defendants. To begin with, throughout the relevant period, The Christ Hospital and The Health Alliance established procedures to ensure compliance with all health care regulations. They maintained a compliance policy. (Hanover Dep. at 35-36, App. 107-08; Dep. Ex. 214, App. 443.) Any manager who had concerns could contact the compliance officer, Christa Nordlund, or call legal counsel directly. (Hanover Dep. at 42-43, App. 109-10; Tempel Dep. at 54-56, App. 258-60.) Likewise, each senior hospital officer acknowledged that the hospital had a duty to comply with the Anti-Kickback Statute. (Croushore Dep. at 85-86, App. 65-66; Dep. Ex. 6 at App. 369.) And, in response to a fraud alert, the compliance officer sent a memo instructing managers that the Anti-Kickback Statute prohibited them from giving referral sources items of value for free or at a discount. (Dep. Ex. 225, App. 445.) These general efforts prohibit a finding that defendants deliberately ignored or recklessly disregarded compliance obligations. *See Perales*, 243 F. Supp. 2d at 866 (finding that defendants were not deliberately ignorant when they "received and considered relevant publications in this area of the law, established a corporate compliance committee, and routinely consulted counsel in drafting the contracts and agreements").

Against that backdrop, the United States' evidence on the panel-time issue does not establish a jury question. For starters, Tempel, the individual who developed the hospital's allocation formula, always believed the method was a "legal process." (Tempel Dep. at 43, App. 256.) He had spoken with an attorney about panel. (*Id.* at 57, App. 261.) He also received the specific memo on the Anti-Kickback Statute from the compliance officer. (*Id.* at 59, App. 262.) That memo, of course, could not possibly have applied to panel because it indicated that payments to physicians must be at fair market value. (Dep. Ex. 225, App. 445.) That would

suggest that the hospital would have to obtain money from physicians for their work in the Heart Station. (*See* Tempel Dep. at 59, 83-84, App. 262, 266-67.)

Given Tempel's diligence, Wietholter's 1996 memo to Von Zychlin mentioning legal challenges cannot establish a jury question. The memo noted that Tempel's formula had "been challenged over the years and potentially could put [the hospital] at risk legally" but that opening up panel to all cardiologists was "an undesirable alternative." (Dep. Ex. 2 at 2, App. 335.) Von Zychlin did not believe the accusations had anything to do with the Anti-Kickback Statute, and felt only that Fry had been threatening to sue, as he often did. (Von Zychlin Decl. ¶ 5, App. 1012; *see, e.g.*, Fry Dep. at 10-11, App. 829-30; Dep Ex. 90, App. 810.)

In any event, even if that memo could be interpreted to suggest that parties had raised Anti-Kickback Statute challenges when interpreted in the United States' favor, that still does not create a jury question. It is well established that "where disputed legal issues arise from vague provisions or regulations, a [defendant's] decision to take advantage of a position can not result in his filing a 'knowingly' false claim." *Southland*, 326 F.3d at 682; *see Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996) ("[T]o take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful.") (internal quotation marks omitted); *United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 952 (S.D. Tex. 2007) (holding that defendant's "failure to respond differently to the concerns that Relator raised" could not establish a knowing violation given vague provisions), *aff'd*, 2008 U.S. App. LEXIS. 17038 (5th Cir. Aug. 7, 2008).

At most, that is all administrators did here. It was an "undesirable alternative" to open panel to all staff (Dep. Ex. 2 at 2, App. 335), because doing so had resulted in patient-care concerns. (Tempel Dep. at 52, App. 257; S. McDonald Dep. at 16-17, App. 181-82.) The memo

identifies these concerns. (Dep. Ex. 2 at 2, App. 335.) To act in the face of the alleged legal risk, then, falls squarely within the law that defendants do not knowingly submit a false claim by "tak[ing] advantage of" vague provisions. *Southland*, 326 F.3d at 682. Indeed, Von Zychlin knew that hospitals routinely looked to volumes for staffing decisions so that fact did not raise any compliance concerns. (Von Zychlin Decl. ¶ 4, App. 1011; *see* Ronning Expert Report at 31, App. 907.) Because the use of volume metrics for staffing decision was "acceptable standard procedure," his "failing to secure a legal opinion, without more, [was] not the type of deliberate ignorance that can form the basis for a FCA lawsuit." *Quirk*, 278 F.3d at 768.

Nor does Seim's "failure to respond differently to the concerns that Relator [Fry] raised" in late 1999 create a jury issue. *Gudur*, 512 F. Supp. 2d at 952. To begin with, Dr. Jennings denies telling Fry in 1999 that lawyers had indicated the current system for allocating panel was illegal. (Jennings Decl. ¶ 3, App. 997.) To the contrary, Jennings indicated that the hospital would be looking into the issue in the future. (*Id.*) And Jennings did, in fact, meet with a hospital lawyer and administrators after his meeting with Fry. (*Id.* ¶ 4, App. 997.)

Yet even accepting as true Fry's hearsay, the United States still has not created a material dispute of fact. After all, even if lawyers had indicated that the current allocation method was illegal, as Fry suggested, "there was nearly a year of effort that was follow-up" in response to Fry's complaints. (Seim Dep. at 70-71, App. 207.) And it is undisputed that Seim ultimately *changed* the method Fry claimed was illegal by outsourcing responsibilities to MDA after a legal review. (*Id.* at 23-24, 103, App. 200-01, 210.) After the change, because the hospital "had gone through a process that [he] thought was fair in terms of selecting another group to do the panel assignments," Seim believed that MDA could use volumes without any compliance concerns. (Seim Dep. in *UIMA v. MDA* at 61, App. 224; Hanover Dep. at 66-69, App. 111-14; Seim Dep.

at 166, App. 217.) Seim thus engaged in a good-faith effort to assure both regulatory compliance and fairness.

Dr. Broderick, MDA's business manager, believed the same. As a physician, he relied upon legal counsel "to take care of whatever things that [MDA] needed from a compliance standpoint." (Broderick Dep. at 204, App. 31.) He repeatedly indicated to numerous lawyers that MDA used volume statistics in allocating panel. (*Id.* at 207, 213-15, App. 32-35.) Yet lawyers never raised concerns. He instead recalls them indicating that physicians could "distribute [panel] how [they'd] like" because MDA was "an independent group" from the hospital. (*Id.* at 207, App. 32.) His reliance on lawyers for MDA's compliance obligations and their failure to raise concerns over the manner that MDA allocated panel time negate the possibility that Broderick knowingly or recklessly violated the law.

Finally, administrators Croushore, Morneault, and Hayes acted appropriately in late 2003 when Dr. Hattemer raised questions about the MDA relationship. They "listened to [his] concerns," (Hattemer Dep. at 35, App. 124), and, as they were new to the issue, had already sought compliance advice. (Morneault Dep. at 88-89, App. 192; Croushore Dep. at 155, App. 69.) At no point did they believe their conduct in providing MDA volume data was illegal. (Morneault Dep. at 89, App. 192; Hayes Dep. at 249, App. 140; *see* Hattemer Dep. at 49, App. 127.) They thought that, at most, there may be a "risk from a compliance standpoint" because the issue fell within a legal "gray area." (Morneault Dep. at 89, 124, App. 192, 194.) But again, "[t]o take advantage of a [legal gray area], as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful." *Hagood*, 81 F.3d at 1478 (internal quotation marks omitted). As such, the United States lacks sufficient evidence to show that defendants knowingly submitted false claims.

C. The United States Lacks Evidence That Defendants' Alleged Violations Of The Anti-Kickback Statute Were Material To Its Payment Decisions.

The United States has also presented no evidence that the manner in which panel was allocated affected its decision to pay defendants' claims. Notably, to support False Claims Act liability, the United States must show that the alleged violation of the Anti-Kickback Statute was "material" to its payment decision. *See A+ Homecare*, 400 F.3d at 444. A fact is material "if it has a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed." *Id.* at 445 (internal quotation marks omitted).

Not all false claims are material. Instead, "a materiality requirement holds that only a subset of admittedly false claims is subject to False Claims Act liability." *Mikes*, 274 F.3d at 697. In other words, the materiality requirement is not satisfied even if compliance with the Anti-Kickback Statute was *generally* a condition of payment, which it was not for the reasons explained above. *See supra* Section II.A.2. Instead, the United States must also present evidence that the *specific* violation had a natural tendency to influence its payment decisions. It has not done so, entitling defendants to summary judgment.

Indeed, the only evidence on this issue illustrates that the manner that administrators and then MDA allocated panel time did not materially affect the United States' payment decisions. The United States never withheld payment based on suspected Anti-Kickback Statute violations. (*See* United States' Admissions at 39, App. 741.) Furthermore, as of December 31, 2004, the United States never issued fraud alerts specifically identifying staffing issues like allocating panel time as implicating the Anti-Kickback Statute. (*See id.* at 20, 35, App. 722, 737.) Rather, it is only recently that the United States has decided to apply the statute to such decisions.

Also of note, the United States learned how MDA allocated panel time no later than October 2003 when it instructed a doctor to wear a wire to MDA meetings. (*See* Toltzis Dep. at

124, App. 274; Dep. Exs. 257-58, App. 826-27.) Yet, armed with this knowledge, the United States admits that it still never told any Medicare contractor to stop paying defendants' claims, further illustrating that MDA's methodology did not, in fact, have any effect on the United States' payment decisions once it learned these facts. (*See* United States' Admissions at 39, 42, 45, App. 741, 744, 747.) At the least, the United States has failed to come forward with evidence to "make a showing sufficient to establish the existence of" this materiality "element." *Celotex*, 477 U.S. at 322.

To be sure, in its opinion denying the motion to dismiss, this Court noted that "violations of the Anti-Kickback Statute and Stark Laws are material as a matter of law." (R.95 at 26 (citing *Rogan*, 517 F.3d at 452).) But the Court's opinion relied on the belief that this case involves Stark allegations. (*Id.* at 2.) It does not. (*See* R.53 at 21-23.) And the case that it cited, *Rogan*, held only that violations of the *Stark Law* were material as a matter of law. 517 F.3d at 452. The *Rogan* court did so because the Stark Law conditions payment on compliance. 42 U.S.C. § 1395nn(g)(1). As such, "[t]estimony from a claims-processing officer along the lines of 'I follow the law' is not required" when Stark violations are at issue. 517 F.3d at 452.

In contrast, violations of the Anti-Kickback Statute are not material as a matter of law. As described above, the government "does not always prosecute alleged violations of the Medicare Anti-Kickback [Statute] which arguably might be covered by its broad proscriptions." *Sharp*, 2001 WL 1035720, at *7. Yet if Anti-Kickback Statute compliance was always material, relators could usurp these federal policy decisions by filing False Claims Act suits when enforcement authorities decline to prosecute. To avoid that result, courts have noted that "'technical violations' of the anti-kickback statute" fall outside the False Claims Act because the plaintiff "must plead *and prove* the materiality of the underlying violation to state a claim."

Sharp, 2001 WL 1035720, at *10 (emphasis added); *see United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 246 F.R.D. 322, 325 (D.D.C. 2007) (permitting defendant to retain former government official as expert to testify "that compliance with the Anti-Kickback Statute was not a condition precedent to the government's decision to pay Medicare claims"). A plaintiff, therefore, must present evidence that the alleged Anti-Kickback Statute violation could have affected the payment decision. Because the United States has not done so, defendants are entitled to summary judgment on materiality grounds as well.

D. The United States' Common-Law Claims Fail For The Same Reasons.

In light of the lack of a genuine fact issue on these False Claims Act elements, the United States' common-law claims of payment by mistake, unjust enrichment, and disgorgement cannot stand. To establish payment by mistake, the United States must show money was "wrongfully, erroneously, or illegally paid," and unjust enrichment similarly requires the government to prove that it would be "unjust and inequitable" to permit a defendant to retain a benefit. *United States v. Guy*, No.1:05-cv-2605, 2006 U.S. Dist. Lexis 45045, at *29, *33 (N.D. Ohio July 3, 2006). In contrast, "[d]isgorgement is a remedy for an unjust enrichment action, not an independent cause of action." *In re Wiand*, No 8:05-cv-1856, 2007 U.S. Dist. Lexis 24069, at *8 (M.D. Fla. March 27, 2007); *SEC v. Blavin*, 760 F.2d 706, 713 (6th Cir. 1985) (noting that "purpose of disgorgement is to force a defendant to give up the amount by which he was unjustly enriched") (internal quotation marks omitted).

Where, as here, the United States adds common-law claims on top of False Claims Act counts, the common-law claims cannot stand independent of the False Claims Act counts. *See United States v. Medica Rents Co. Ltd.*, No 03-11297, 2008 U.S. App. Lexis 17946, at *12-13 (5th Cir. Aug. 19, 2008) (affirming summary judgment on payment by mistake and unjust enrichment claims where evidence did not support inference that defendants knowingly

submitted false claims). That is because, if a plaintiff cannot meet the False Claims Act's elements, a defendant's "retention of benefits [conferred in payment of the claims] is equitable." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1035 (D. Nev. 2006); *see United States v. Reed*, No. 01C6535, 2003 U.S. Dist. Lexis 2659, at *11 (N.D. Ill. Feb. 25, 2003). Thus, because the United States has not demonstrated a fact dispute on the False Claims Act's elements, no fact dispute exists over whether defendants were paid by mistake or unjustly enriched. *See Medica Rents*, 2008 U.S. App. Lexis 17946, at *12-13. And disgorgement, a remedy, obviously cannot stand alone.

III. AT THE LEAST, THE COURT SHOULD GRANT DEFENDANTS SUMMARY JUDGMENT AS TO MANY OF THE ALLEGED FALSE CLAIMS.

Even if the Court concludes that a fact dispute exists during some of the relevant period, it should at least grant defendants summary judgment on many of the reimbursement claims at issue. To begin with, it cannot hold defendants liable when MDA allocated panel time because, during that time, The Christ Hospital and The Health Alliance had no authority to offer panel time to induce referrals. In addition, the United States has failed to present sufficient evidence to prove that an Anti-Kickback Statute violation tainted many of the hundreds of thousands of allegedly false claims. Finally, it has failed to present evidence to show defendants violated the "reverse false claim" provisions in 31 U.S.C. § 3729(a)(7).

A. The United States Cannot Hold Defendants Liable During The Time That MDA Allocated Panel.

Even if the Court believes that a fact dispute exists during some of the period at issue, it should at least grant defendants summary judgment for the period that MDA allocated panel time. Because MDA allocated panel time between 2001 and 2004, The Christ Hospital and The Health Alliance did not "offer[] or pay[]" panel time to induce referrals during those years. 42 U.S.C. § 1320a-7b(b)(2). Both the initial contract and the addendum unequivocally gave MDA the

"exclusive" right to perform all Heart Station services and make all panel allocations. (*See* Dep Ex. 65 at 1, App. 397; Dep. Ex. 69 at 1, App. 404; *see also* Renjilian Expert Report at 21, App. 853.)

The United States, therefore, must rely on its conspiracy count to create an issue for the jury during this period. (R.53 at 25.) Under the False Claims Act's conspiracy provision, 31 U.S.C. § 3729(a)(3), the United States must prove that defendants "agreed upon a fraud scheme" and "intended 'to defraud the Government' by that scheme." *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2130 (2008). This provision thus establishes a higher scienter standard than other False Claims Act provisions because the United States must show that defendants entered into an agreement with "a specific intent to defraud the Government." *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343 (5th Cir. 2008).

Given that the United States lacks evidence to show that defendants acted "knowingly," *see supra* Section II.B, it certainly falls short in meeting this more demanding element. For starters, the evidence shows that MDA physicians came up with MDA's allocation method separate from the hospital.[16] The evidence likewise illustrates that MDA made its annual allocation decisions at meetings in which no hospital personnel attended. (*See* Dep. Ex. 129, App. 411, Dep. Ex. 177, App. 425; Dep. Ex. 183, App. 428.)

In fact, the United States secret recordings of MDA meetings revealed that no hospital administrators attended. (Broderick Dep. at 308-10, App. 48-50; see Dep Ex. 247 at 7-8, App. 483-84; Dep. Ex. 248 at 6, App. 542.) Indeed, during those meetings, the MDA physicians discussed whether the administration would honor the MDA contract by continuing to give them

[16] (*See* Abbottsmith Dep. at 44, App. 5; Broderick Dep. at 153, 266, App. 27, 39; Hattemer Dep. at 29-30, App. 120-21; Seim Dep. at 168, App. 217; Wietholter Dep. in *UIMA v. MDA* at 25, App. 313.)

the exclusive authority to allocate panel time. (Dep. Ex. 248 at 11-15, App. 547-551.) They recognized that if the administrators broke the contract, they would have "grounds to potentially sue at that point" (*id.* at 13, App. 579), demonstrating that they too believed that "the disposition of those [panel] services [was] purely at [their] whim," (*id.* at 35, App. 571). MDA's internal threats to sue The Christ Hospital and The Health Alliance negate the possibility that those parties were acting in concert to defraud the United States.

That the hospital provided volume data to MDA each year does not change things, given that, as the evidence shows, MDA physicians decided upon the volume-based formula independent of the hospital. Indeed, MDA often decided to rely on different volume statistics in its internal discussions than it had in prior years, requiring Wietholter to re-run different data and confirming that MDA physicians chose the statistics on which they wanted to rely without hospital involvement. (Wietholter Dep. in *UIMA v. MDA* at 26-29, App. 314-17.) Cementing that fact are the secretly recorded MDA meetings at which MDA physicians complained that it was "like pulling teeth" in trying to obtain the data they requested from the hospital. (Dep. Ex. 248 at 10, App. 546.) And when it was provided, it "was missing a whole bunch of DRGs" that the doctors had wanted, requiring them to ask the hospital for it again. (*Id.*)

Finally, defendants could not have harbored the specific intent to defraud because the evidence shows that they reasonably believed that MDA, as a separate entity, could allocate panel time in any manner it chose. As described above, there is no dispute that The Christ Hospital and The Health Alliance conducted review "relative to the legality of [the] process that [the hospital] [went] to" when it switched to MDA. (Seim Dep. at 23-24, App. 200.) And at no point, it bears noting, did anyone at the hospital believe that the hospital broke any laws by providing MDA with volume data. (Hanover Dep. at 66-68, App. 111-13; Seim Dep. at 166,

App. 217; Morneault Dep. at 89, App. 192; Hayes Dep. at 249, App. 140.) Similarly, Dr. Broderick repeatedly told MDA's lawyers the manner in which MDA allocated panel time, and they did not object. (Broderick Dep. at 213-15, App. 33-35.) Far from objecting, they instead indicated MDA could "distribute [panel] how [they'd] like" because it was "an independent group." (*Id.* at 207, App. 32.) Given this evidence, the United States cannot satisfy the specific-intent-to-defraud standard required to make out a conspiracy allegation. As such, summary judgment is appropriate during the time that MDA allocated panel.

B. The United States Cannot Present Any Claim To The Jury For Which It Lacks Sufficient Evidence To Prove All Elements Of An Anti-Kickback Statute Violation.

The United States falls short on the evidence necessary to present its far-reaching damages theory to the jury. The United States seeks to hold The Christ Hospital, The Health Alliance, and Ohio Heart jointly liable for essentially all claims submitted for cardiac services performed at The Christ Hospital from 1997 through the first quarter of 2004, whether those claims were submitted by The Christ Hospital, The Health Alliance, Ohio Heart, MDA, or any other third-party cardiologist, cardiac surgeon, or physician. (*See* R.53 at 21-22; R.217 at 2-3.) But the United States has not presented sufficient evidence on the hundreds of thousands of claims it alleges are false. A claim can only be false if the services underlying it were tainted by an Anti-Kickback Statute violation. That is the entire basis for the "legally false claims" theory. *See Mikes*, 274 F.3d at 696-97. As a result, the United States must present evidence to meet every element of the Anti-Kickback Statute *for each claim* it alleges is false. But it lacks sufficient evidence on most of the allegedly false claims.

For starters, the United States has not presented sufficient evidence with respect to all claims for services by physicians who did not know the manner that panel was allocated. It is undisputed, for example, that Relator Fry did not know how panel was allocated until mid-2002,

at which point he had retired and his lawyer asked him to bring this case. (Fry Dep. at 70-72, 106-09, App. 85-87, 92-95.) He specifically admitted that the hospital never offered him panel time to induce him to refer patients to the hospital. (*Id.* at 108-09, App. 94-95.) Given these admissions by the relator himself, the United States cannot hold defendants liable for claims that they or Fry submitted for his services.

And Fry represents just the tip of the iceberg. The majority of physicians who allegedly provided illegal services had no idea how panel was assigned, at least during some portion of the relevant period.[17] Some of these physicians, for example, "probably couldn't even find Christ Hospital," let alone describe the panel allocation process there. (Wietmarschen Dep. at 71, App. 330.) And the United States has presented little if any evidence that other physicians alleged to be unlawfully "induced" by the volume-based formula knew how panel time was assigned.[18] At this stage, the United States can no longer "rest on the mere allegations in [its] pleadings." *McKenzie*, 219 F.3d at 512. Given this dearth of evidence, the claims for services by these

[17] *See* Behrens Decl. ¶ 4, App. 975; Broderick Dep. at 16-18, App. 15-17; Caples Decl. ¶ 4, App. 979; Choo Decl. ¶ 5, App. 981; Chung Decl. ¶ 4, App. 983; Clarke Decl. ¶ 4, App. 985; English Decl. ¶ 4, App. 987; Forman Decl. ¶ 4, App. 989; Fry Dep. at 106-07, App. 92-93; Glassman Decl. ¶ 4, App. 991; Hattemer Dep. at 8-9, App. 117-18; Henthorn Dep. at 23, 34-35, App. 144, 149-50; Hunter Decl. ¶ 4, App. 993; Ivey Decl. ¶ 4, App. 995; Jenike Dep. at 11-12, App. 157-58; Kereiakes Decl. ¶ 4, App. 999; Murtaugh Decl. ¶ 4, App. 1001; Pelberg Decl. ¶ 4, App. 1003; Schneider Decl. ¶ 4, App. 1005; Stewarth-Dehner Decl. ¶ 4, App. 1007; Thoresen Decl. ¶ 4, App. 1009; Whang Dep. at 20-21, App. 307; Waller Decl. ¶ 4, App. 1013; Wietmarschen Dep. at 29-30, 65-66, App. 324-25, 328-29; *see also* Renjilian Expert Report at 22, App. 854.)

[18] (Dep. Ex. 162, App. 418.) Of the doctors that the United States has identified as being unlawfully induced in violation of the Anti-Kickback Statute, it has presented no evidence at least with respect to: Razavi, Waisbluth, Penmesta, Srinivasan, Srivastava, Skale, Gerlinger, Sulkin, Hauger, Tarnuta, Drake, Reed, Tondow, Bhandari, Ternizer, Wayne, Loughery, Schloss, Ghazi, Daoud, Answini, Long, Burroughs, Hackworth, Held, Mashny, Wilson, Rajasekhar, Suna, Gupta, Kirkham, Mehlman, Shea, Hirsh, Coith, Snitzer, Strickmeyer, Jung, Lewis, Steinberg, or Fisher. (*See id.*)

physicians, like the claims for services by Fry, must be excluded from the United States' damages theory.

In addition, to prove an Anti-Kickback Statute violation, the "focus is on whether [the thing offered or paid] constitutes a thing of value to the *intended recipient* in whatever form offered or paid." (Jury Instructions in *United States v. MacKenzie*, No. 01-10350, at *48 (D. Mass. 2004) (emphasis added), App. 698.) Here, many physicians who treated patients at the hospital placed no value on the opportunity to perform work on its Heart Station panels because of the significant opportunity costs involved.[19] As such, the claims predicated upon all these physicians' services must also be excluded from the United States' damages.

To this date, moreover, the United States has not produced the claims submitted by third parties for which it seeks to hold defendants liable. (*See* R.228 at 2-4.) Given its failure to produce these claims, it has forfeited its right to use them as damages. After all, as Magistrate Judge Black indicated, "[t]he United States has had sufficient time to assert its claims and damages and may not, after the discovery deadline has passed, allege additional claims or damages. (*Id.* at 4.)

The United States' complaint also seeks to hold defendants liable for claims submitted under the TRICARE program. (*See* R.53 at 12-13, 21-22.) But it has now expressly indicated that it will not seek any TRICARE claims as damages. (*See, e.g.*, 08/28/09 Seibel Letter at 2, App. 702.) The Court must grant summary judgment on these claims as well.

Finally, the United States seeks to hold The Christ Hospital, The Health Alliance, and Ohio Heart liable for claims submitted by MDA. But it has made no showing that MDA ever

[19] (*See* Hattemer Dep. at 32, 70-71, App. 123, 131-32; Henthorn Dep. at 31, 33-34, App. 147-49; Ivey Decl. ¶ 5, App. 995; Jenike Dep. at 20, 82-83, App. 161, 164-65; Snavely Dep. at 14, App. 230; Suresh Dep. at 74, App. 239; Whang Dep. at 19-20, App. 307; Wietmarschen Dep. at 31, App. 325.)

certified that any of the hundreds of thousands of claims that it submitted were in compliance with the Anti-Kickback Statute. (*See* R.217 at 8.) Given that the "implied certification" doctrine does not apply with respect to the Anti-Kickback Statute, *Urbanek*, 2003 U.S. Dist. LEXIS 27469, at *23, the United States cannot seek to hold The Health Alliance, The Christ Hospital, or Ohio Heart liable for these MDA claims.

C. The United States' "Reverse False Claim" Count Fails Because Defendants' Obligation To Pay It Arises Solely From Their Allegedly False Claims.

Count IV in the United States' complaint, which alleges "reverse false claims" under 31 U.S.C. § 3729(a)(7), also cannot stand. (*See* R.53 at 25-26.) The False Claims Act's reverse-false-claim provision imposes liability on a defendant who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). Unlike in the typical context, "[i]n a reverse False Claims Act suit, there is no improper payment by the government to a defendant, but rather there is an improper reduction in the defendant's liability to the government." *Marcy*, 520 F.3d at 390.

As a required element, the United States must show that the defendant had an "obligation to pay" it money. That obligation must exist separate from the allegedly fraudulent conduct. Where, on the other hand, "an obligation arises if and only if a defendant makes a false statement or files a false claim . . . , an action under [31 U.S.C. § 3729(a)(7)] will not lie." *Am. Textile*, 190 F.3d at 738. Indeed, "[t]here is widespread agreement that the making or using of the false record or statement is not sufficient in itself to create an obligation under § 3729(a)(7)." *United States ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1195 (10th Cir. 2006). That is so because, if an alleged false statement to obtain funds could itself create an obligation to repay those funds, it "would result in every violation of § 3729(a)(1) necessarily resulting in a violation

of § 3729(a)(7) as well." *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522, 528 (M.D. Pa. 2008).

Despite this prohibition, the United States still seeks to bootstrap its reverse-false-claim count on top of the other counts. Specifically, it relies upon the false certifications to allege that defendants both: (1) submitted false claims (in violation of § 3729(a)(1)-(2)); and (2) made false statements to avoid repaying the same funds (in violation of § 3729(a)(7)). But the United States cannot have it both ways. Because it has not uncovered evidence that defendants had an obligation to pay independent of their allegedly false certifications, Count IV is fatally flawed

CONCLUSION

For the foregoing reasons, the Court should grant defendants summary judgment on all counts. At the least, the Court should grant them partial summary judgment on certain counts and certain claims.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 24, 2009, a true and correct copy of the foregoing was electronically filed with the Clerk of the United States District Court for the Southern District of Ohio, Western Division, using the CM/ECF system, which will send notification of such filing to the following counsel of record:

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